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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR PARTS 1300, 1301, 1304, 1305, 1307, 1317, and 1321

[Docket No. DEA-316]

RIN 1117-AB18

Disposal of Controlled Substances

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: This rule proposes requirements to govern the secure disposal of controlled substances by both DEA registrants and ultimate users. These regulations would implement the Secure and Responsible Drug Disposal Act of 2010 (Pub. L. 111-273) by expanding the options available to collect controlled substances from ultimate users for purposes of disposal to include: take-back events, mail-back programs, and collection receptacle locations. These proposed regulations contain specific language to continue to allow law enforcement agencies to voluntarily conduct take-back events, administer mail-back programs, and maintain collection receptacles. These regulations propose to allow authorized manufacturers, distributors, reverse distributors, and retail pharmacies to voluntarily administer mail-back programs and maintain collection receptacles. In addition, this proposed rule expands the authority of authorized retail pharmacies to voluntarily maintain collection receptacles at long term care facilities.

This proposed rule also reorganizes and consolidates existing regulations on disposal, including the role of reverse distributors.

DATE: Electronic comments must be submitted and written comments must be postmarked on or before [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA-316” on all electronic and written correspondence. DEA encourages all comments be submitted electronically through <http://www.regulations.gov> using the electronic comment form provided on that site. An electronic copy of this document is also available at the <http://www.regulations.gov> website for easy reference. Paper comments that duplicate the electronic submission are not necessary as all comments submitted to <http://www.regulations.gov> will be posted for public review and are part of the official docket record. Should you, however, wish to submit written comments via regular or express mail, they should be sent to the Drug Enforcement Administration, Attention: DEA Office of Diversion Control (OD/DX), 8701 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION, CONTACT: John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 307-4654.

SUPPLEMENTARY INFORMATION

Posting of Public Comments:

Please note that all comments received are considered part of the public record and are made available for public inspection online at <http://www.regulations.gov> and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you would like to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you would like to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted, and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the

agency's public docket file in person by appointment, please see the "For Further Information" paragraph.

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EXECUTIVE SUMMARY

Purpose of the Regulatory Action

On October 12, 2010, the Secure and Responsible Drug Disposal Act of 2010 (Disposal Act) was enacted (Pub. L. 111-273, 124 Stat. 2858). Before the Disposal Act, ultimate users who wanted to dispose of unused, unwanted, or expired controlled substance pharmaceuticals had limited disposal options. The Controlled Substances Act (CSA) only permitted ultimate users to destroy those substances themselves, for example by flushing or discarding, or to dispose of such substances by surrendering them to law enforcement or by seeking assistance from the U.S. Drug Enforcement Administration (DEA). These restrictions resulted in the accumulation of controlled substances in household medicine cabinets that were available for abuse, misuse, and accidental ingestion. The Disposal Act amended the CSA to authorize ultimate users to deliver their controlled substances to another person for the purpose of disposal in accordance with regulations promulgated by the Attorney General. 21 U.S.C. 822(g) and 828(b)(3). The Attorney General delegated responsibility for promulgating the Disposal Act implementing regulations to DEA. These proposed regulations expand the entities to which ultimate users may transfer unused, unwanted, or expired controlled substances for the purpose of disposal, as well as the methods by which such controlled substances may be collected. Specified entities may voluntarily administer any of the authorized collection methods in accordance with these proposed regulations.

Summary of the Major Provisions of the Regulatory Action

DEA is proposing new regulations for the disposal of controlled substances by ultimate users in accordance with the Disposal Act. In drafting the implementing

regulations, DEA considered the public health and safety, ease and cost of program implementation, and participation by various communities. To this end, DEA found that in order to properly address the disposal of controlled substances by ultimate users, it was necessary to conduct a comprehensive review of DEA policies and regulations related to each element of the disposal process, including the transfer, delivery, collection, destruction, return, and recall of controlled substances, by both registrants and non-registrants (e.g., ultimate users). The reverse distributor registration category, which is pertinent to the process of registrant disposal, was included in this comprehensive review. These regulations will be incorporated into a new part 1317 on disposal.

The goal of this proposed new part on disposal, consistent with Congress's goal in passing the Disposal Act, is to set controlled substance diversion prevention parameters that will encourage public and private entities to develop a variety of methods for collecting and destroying controlled substances in a secure, convenient, and responsible manner. Also consistent with Congress's goal in passing the Disposal Act to decrease the amount of controlled substances introduced into the environment, particularly into the water, these regulations provide individuals various additional options to dispose of their unwanted or unused controlled substances beyond discarding or flushing the substances. As a result of these regulations, the supply of unused controlled substances in the home should decrease, thereby reducing the risk of unintentional diversion or harm.

Ultimate User Disposal

This rule proposes three voluntary options for ultimate user disposal: (1) take-back events, (2) mail-back programs, and (3) collection receptacles. In addition to ultimate users, individuals lawfully entitled to dispose of ultimate user decedent's

property are authorized to dispose of the ultimate user's substances by utilizing any of the three options for disposal. All of the proposed collection methods are voluntary and no person is required to establish or operate a disposal program.

DEA proposes specific language that will continue to authorize federal, state, tribal, and local law enforcement agencies, either independently or in partnership with private entities or community groups, to voluntarily hold take-back events and administer mail-back programs. DEA also proposes to authorize certain registrants (manufacturers, distributors, reverse distributors, and retail pharmacies) to be "collectors," with authorization to conduct mail-back programs. All mail-back programs must provide specific mail-back packages to the public, either at no cost or for a fee, and collectors that conduct mail-back programs must have and utilize an on-site method of destruction.

Finally, DEA proposes that law enforcement agencies voluntarily maintain collection receptacles at that agency's physical location and to authorize collectors to maintain collection receptacles at their registered location. Retail pharmacies that are authorized to be collectors may maintain collection receptacles at long term care facilities (LTCFs). LTCFs are permitted to dispose of controlled substances on behalf of an ultimate user that resides or has resided at that LTCF only through a collection receptacle that is maintained by a retail pharmacy at that LTCF.

DEA proposes to allow all controlled substances collected through take-back events, mail-back programs, and collection receptacles to be comingled with non-controlled substances. Controlled substances collected by collectors may not be individually counted or inventoried. In addition, DEA proposes various collection security and recordkeeping requirements.

DEA appreciates that there is a cost to voluntarily providing these methods of collection and destruction. DEA notes that some state and local pharmaceutical disposal programs receive funding and other support from numerous sources, including conservation groups, local governments, state grants, and public and private donations. These expanded methods of disposal benefit the public by decreasing the supply of controlled substances available for misuse, abuse, and accidental ingestion, and protect the environment from potentially harmful contaminants. However, other advantages may accrue directly to those entities that opt to maintain a disposal program. For example, those authorized registrants that choose to maintain collection receptacles may be enhanced by the increased consumer presence at their registered locations and the goodwill that develops from providing a valuable community service. In addition, the proposed regulation specifies that mail-back program collectors may partner with third parties to make mailers available to the public. Those authorized registrants that choose to administer mail-back programs may gain from the opportunity to distribute to consumers promotional, educational, or other informational materials with the mailers.

Registrant Disposal

DEA proposes to delete the existing rule related to registrant disposal, 21 CFR 1307.21, and incorporate similar requirements on proper disposal procedure, security, and recordkeeping in a new part 1317 on disposal. DEA proposes these changes in order to provide consistent disposal procedures for each registrant category, regardless of geographic location. In addition, DEA proposes to modify existing DEA Form 41 to record the destruction of controlled substances that remain in the closed system of distribution and to account for registrant destruction of controlled substances collected

from ultimate users and other non-registrants outside the closed system pursuant to the Disposal Act.

Reverse Distributors

DEA proposes revised regulations for reverse distributors that are clear, consistent, and consolidated into one part. Reverse distributors are often the last registrant to possess controlled substances prior to destruction because they are at the end of the closed system and the same recordkeeping safeguards that exist when controlled substances are distributed between registrants are not present. Because reverse distributors routinely acquire controlled substances for destruction from other registrants and may also be authorized as collectors, reverse distributors accumulate greater amounts of controlled substances that are destined for destruction in comparison to other registrants. DEA believes that the proposed regulations will help reverse distributors comply with the Controlled Substances Act in a manner that effectively decreases the risk of the diversion of controlled substances during the disposal process. DEA proposes to revise the definition of reverse distributor in addition to proposing new procedures that reverse distributors must follow to acquire controlled substances from registrants and other security and recordkeeping requirements.

Return and Recall

DEA proposes to delete the existing rule on return and recall, 21 CFR 1307.12, and incorporate into a new part 1317 clarified and separate return and recall requirements for registrants and non-registrants.

Methods of Destruction

DEA proposes a standard of destruction – non-retrievable – for persons that

intend to destroy controlled substances. In particular, DEA is not requiring a particular method of destruction, so long as the desired result is achieved. This standard is intended to allow public and private entities to develop a variety of destruction methods that are secure, convenient, and responsible, consistent with preventing the diversion of such substances. Destruction of controlled substances must also meet all other applicable federal, state, tribal, and local laws and regulations.

Background

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and the Controlled Substances Import and Export Act (21 U.S.C. 801- 971), as amended, and referred to as the Controlled Substances Act (CSA).¹ DEA publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for a sufficient supply of controlled substances and listed chemicals for legitimate medical, scientific, research, and industrial purposes. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety. To this end, controlled substances are classified into one of five schedules based upon: the potential for abuse, currently accepted medical use, and the degree of dependence if abused. 21 U.S.C. 812. Listed chemicals are separately classified based on their use and importance to the manufacture of controlled substances

¹ The Attorney General's delegation of authority to DEA may be found at 28 CFR 0.100.

(List I or List II chemicals). 21 U.S.C. 802(33) – (35).

The CSA establishes a closed system of distribution that requires DEA to monitor and control the manufacture, distribution, dispensing, import, and export of controlled substances and listed chemicals until they reach their final lawful destination. The secure destruction of unused, recalled, tainted, expired, or otherwise unwanted controlled substances is essential to preventing the diversion of controlled substances into the illicit market.

In order to maintain this closed system of distribution, persons that manufacture, distribute, dispense, import, export, or conduct research or chemical analysis with controlled substances and listed chemicals are required to register with DEA at each principal place of business or professional practice. Persons registered with DEA are permitted to possess controlled substances and listed chemicals as authorized by their registration and must comply with the applicable requirements associated with their registration. 21 U.S.C. 822.

Not all persons that possess controlled substances are required to register with DEA. For example, a patient who receives a controlled substance pursuant to a lawful prescription, also known as an ultimate user, is not required to register with DEA in order to receive and possess that controlled substance. 21 U.S.C. 822(c)(3); see also 21 U.S.C. 957(b)(1)(C).² The CSA defines an “ultimate user” as “a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.” 21 U.S.C. 802(27).

² 21 U.S.C. 822(c)(3) and 957(b)(1)(C) except “ultimate users” who possess substances for purposes referenced in 21 U.S.C. 802(25); however, “ultimate user” is defined in 21 U.S.C. 802(27).

While Congress envisioned a closed system of distribution that would control a substance from its manufacture or import through the traditional chain of distribution moving from registrant to registrant until it reached its final lawful use (e.g., dispensed to the ultimate user, etc.), it did not account for circumstances in which controlled substances were lawfully dispensed to and possessed by an ultimate user but not fully used. Although ultimate users are exempt from CSA registration requirements for the possession of controlled substances, if they distribute (i.e., deliver or transfer) such controlled substances without the appropriate registration, they are in violation of the CSA.³ Such unlawful distribution includes the transfer of controlled substances for the purpose of disposal.⁴

On October 12, 2010, the Secure and Responsible Drug Disposal Act of 2010 (Disposal Act) was enacted (Pub. L. 111-273, 124 Stat. 2858). The Disposal Act amended the CSA to allow an ultimate user to “deliver” a controlled substance “to another person for the purpose of disposal” if the person receiving the controlled

³ It is unlawful to knowingly or intentionally manufacture, distribute, dispense, or possess with the intent to manufacture, distribute, or dispense, a controlled substance without the appropriate registration. 21 U.S.C. 841(a).

⁴ The terms “disposal,” “dispose,” or “disposition” appear several times in the CSA and its implementing regulations, but these terms are not defined. For example, in the CSA, see 21 U.S.C. 822(g); 824(f) and (g); 826(c), (e), and (f); 827(a)(3) and (d)(1); 842(a)(7); 853(n); 880(a)(2); 881(e)(1); and 958(d)(6); and in the CFR, see 21 CFR 1307.21(b). The term “net disposal,” however, is defined at 21 CFR 1300.01(b). As used, the terms refer to a variety of activities that ultimately result in eliminating the availability of controlled substances for use. For example, within the meaning of the CSA, a controlled substance can be “disposed of” by destruction, return, recall, sale, or through the manufacturing process. The Disposal Act allows an ultimate user to deliver a lawfully obtained controlled substance to another person “for the purpose of disposal.” DEA believes that the ultimate user disposal authorized by the Disposal Act includes the transfer or delivery of controlled substances for purposes of destruction, return, and recall. Such ultimate user activities are consistent with the intent to remove unused, unwanted, tainted, and expired substances from households and out of the reach of children and teenagers thereby reducing the risk of diversion and protecting the public health and safety. As used in this Notice of Proposed Rulemaking, DEA uses the terms “disposal” and “dispose” to refer generally to the wide range of activities that result in controlled substances being unavailable for further use. When necessary to specify a particular activity within the disposal process, the particular activity is identified, e.g., transfer, deliver, collect/collection, return, recall, destroy/destruction.

substance is authorized to receive that substance and the disposal takes place in accordance with regulations issued by the Attorney General to prevent the diversion of controlled substances. 21 U.S.C. 822(g)(1). The Attorney General delegated responsibility for promulgating the Disposal Act implementing regulations to DEA.

In addition to authorizing ultimate users to deliver their controlled substances to another person for the purpose of disposal, the Disposal Act also authorized any person lawfully entitled to dispose of an ultimate user decedent's property to deliver the ultimate user's controlled substance to another person for the purpose of disposal if the ultimate user dies while in lawful possession of the controlled substance. The Disposal Act also gave DEA the ability, by regulation, to authorize long term care facilities (LTCFs) to dispose of controlled substances on behalf of ultimate users who reside or have resided at the LTCF. Congress directed DEA, in promulgating the Disposal Act implementing regulations, to consider the public health and safety, ease and cost of program implementation, and participation by various communities. The implementing regulations may not *require* any person to establish or operate a delivery or disposal program.

History of Disposal of Controlled Substances

In 1970, Congress created the CSA after consolidating more than 50 laws related to the control of narcotics and dangerous drugs. The statute was “designed to improve the administration and regulation of the manufacturing, distribution, and dispensing [and import/export] of controlled substances by providing for a ‘closed’ system of drug distribution for legitimate handlers of such drugs” with criminal penalties for transactions

outside the legitimate chain.⁵ With the enactment of the CSA, the Attorney General delegated the responsibility for promulgating the CSA's implementing regulations to DEA's predecessor, the Bureau of Narcotics and Dangerous Drugs (BNDD).⁶

BNDD recognized that to maintain the closed system of distribution, secure avenues for the destruction of controlled substances were essential. The implementing regulations specifically addressed the issue of the disposal of controlled substances (36 FR 7776, April 24, 1971). In particular, the implementing regulations outlined a process under which any person lawfully in possession of a controlled substance could distribute such substance to the person from whom he/she obtained it or return it to the manufacturer or the manufacturer's registered agent, and created procedures for any person in possession of a controlled substance, with instruction from DEA, to either deliver or transfer the substance to another for destruction, or to destroy that substance themselves. 21 CFR 1307.12 and 1307.21. These procedures have changed little since 1971.

DEA Registrant Disposal – Reverse Distributors

Through the mid-1990s, DEA accepted controlled substances from registrants for destruction or authorized registrants to destroy controlled substances pursuant to 21 CFR 1307.21. Manufacturers also accepted returns of controlled substances from their customers as an additional service. Eventually, a group of brokers emerged with the sole purpose to collect controlled substances from registrants for destruction pursuant to the

⁵ H.R. REP. NO. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4571-4572.

⁶ In 1973, the BNDD was abolished and all BNDD functions were transferred to DEA. Reorganization Plan No. 2 of 1973, 38 FR 18380 (July 2, 1973).

procedures outlined in DEA's regulations.⁷ Initially, this group registered with DEA as distributors and called the services that they provided "reverse distribution." At about the same time, another group emerged called "inventory control processors/auditors" whose primary purpose was to identify expired substances in a registrant's inventory and prepare them for disposal by the registrant pursuant to 21 CFR 1307.21, or return to the person from whom it was obtained or to the manufacturer. This group was not required to register with DEA in order to conduct their activities because they did not take possession of the substances. Any inventory control processors/auditors that wanted to take possession of controlled substances were required to register with DEA as distributors. To reduce the risk of diversion from these activities, and ensure accountability during the disposal process, DEA and the registered distributors entered into memorandums of understanding (MOUs) that outlined acceptable disposal procedures until permanent regulations were finalized.

Initially, DEA proposed to codify these MOUs by issuing a Notice of Proposed Rulemaking to define and register a new category of manufacturer registration called "disposers" that would authorize those registrants to receive controlled substances for the primary purpose of destruction (60 FR 43732, August 23, 1995). This rule was never finalized. In 2003, DEA readdressed the issue of registrant disposal in an Interim Final Rule (IFR) to define and register "reverse distributors" (68 FR 41222, July 11, 2003). In 2005, DEA published a final rule, thereby finalizing a new category of distributor registration called "reverse distributors" (70 FR 22591, May 2, 2005). The final rule authorized reverse distributors to acquire controlled substances from DEA registrants for

⁷The procedures are found today in 21 CFR 1307.21.

the purpose of return to the manufacturer or manufacturer's agent or for processing those substances for disposal in accordance with 21 CFR 1307.21. The final rule also codified security, recordkeeping, reporting, and order form requirements applicable to reverse distributors.

Non-Registrant Disposal

As discussed above, prior to passage of the Disposal Act, the CSA did not address the disposal of controlled substances by ultimate users. Congress envisioned a closed system of distribution that would control a substance from its manufacture or import through the traditional chain of distribution moving from registrant to registrant until it reached its final lawful use (e.g., dispensed to the ultimate user, etc.). The CSA did not, however, account for circumstances in which controlled substances were lawfully dispensed to and possessed by an ultimate user, but not fully used. To this end, the CSA did not authorize the ultimate user to transfer unwanted and unused controlled substances to another person for the purpose of disposal.

Moreover, the CSA did not address the disposal of controlled substances by long term care facilities (LTCFs). DEA defines a LTCF as “a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.” 21 CFR 1300.01(b). Generally, controlled substances are prescribed by a LTCF resident's physician and dispensed by the resident's pharmacist; such controlled substances are owned by the resident. This is in contrast with patients in a hospital where controlled substances are dispensed dose by dose and remain under the possession and control of the registered dispenser, the hospital. Accordingly, a LTCF may secure its residents' controlled substances for custodial purposes only. The controlled substances

remain in the lawful possession of the resident, the ultimate user. As with any other ultimate user, prior to the enactment of the Disposal Act, a LTCF resident in lawful possession of dispensed controlled substances could not distribute those substances to another person, even for the purpose of disposal.

In anticipation of the growing need of ultimate users and LTCFs to dispose of unused and unwanted controlled substances, DEA published an Advance Notice of Proposed Rulemaking to solicit information on the disposal of controlled substances by ultimate users and LTCFs (74 FR 3480, January 21, 2009). Subsequently, as discussed above, on October 12, 2010, the Secure and Responsible Drug Disposal Act of 2010 was enacted.

Existing DEA Regulations

Existing DEA regulations on the disposal of controlled substances are codified at 21 CFR 1307.12 and 1307.21. The process for returns is outlined in 21 CFR 1307.12 and permits any person in lawful possession of a controlled substance to distribute that substance, without being registered to distribute, to the person from whom the substance was obtained or to the manufacturer or manufacturer's registered agent.

The procedure governing the transfer of controlled substances for disposal is outlined in 21 CFR 1307.21. In the existing regulations, any person in possession of any controlled substance that desires or is required to dispose of such substance may request authority and instructions for disposal from the DEA Special Agent in Charge (SAC) in the region in which they are located. The SAC must authorize and instruct applicants to dispose in one of four ways, by: (1) transfer to a DEA registrant authorized to possess the substance; (2) delivery to an agent of DEA or to the nearest DEA office; (3) destruction

in the presence of an agent of DEA or other authorized person; or (4) such other means that the SAC determines to assure that the substance does not become available to unauthorized persons. 21 CFR 1307.21(b).

Registrants requesting authority and instructions from the SAC to dispose of controlled substances must submit to the SAC three copies of DEA Form 41 listing the controlled substances that the registrant would like to dispose. 21 CFR 1307.21(a).

Registrants required to regularly dispose of controlled substances may ask the SAC for authorization to dispose of those substances without prior approval from DEA in each instance if the registrant agrees to keep records of disposal. Further, the SAC may place additional conditions upon the ongoing approval to dispose. 21 CFR 1307.21(c).

Reverse Distributors

DEA currently defines a reverse distributor as “a registrant who receives controlled substances acquired from another DEA registrant for the purpose of – (1) Returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer’s agent; or (2) Where necessary, processing such substances or arranging for processing such substances for disposal.” 21 CFR 1300.01(b). Reverse distributors are required to meet general security requirements, the security requirements applicable to non-practitioners, and specific inventory, recordkeeping, and reporting requirements. DEA registrants are authorized to distribute their lawfully possessed controlled substances to a registered reverse distributor to the extent authorized by their registration and in conformity with the CSA and its implementing regulations. 21 U.S.C. 822(b) and 958(g); See, e.g., 21 CFR 1301.13(e) and 1307.11. Manufacturers, distributors, importers, and practitioners are currently authorized to distribute their

lawfully possessed controlled substances to a reverse distributor without prior authorization from the SAC in the region they are located. 21 CFR 1301.13(e)(i), (ii), (viii) and 1307.11(a)(2).

Law Enforcement Agencies and Ultimate User Take-Back Events

Until DEA finalizes the implementing regulations for the Disposal Act and expanded options for disposal are available, ultimate users may not deliver their lawfully obtained controlled substances to any other person for the purpose of disposal other than by surrender to law enforcement or under the direction of the DEA Special Agent in Charge in the area in which the person is located. In the interim, DEA has established National Take-Back Days.⁸ DEA organized these nationwide one day events as a collaborative effort with state and local law enforcement agencies. The National Take-Back Days provide the public with a convenient and secure way to surrender pharmaceutical controlled substances to law enforcement for destruction.⁹

Prescription Drug Abuse Epidemic

Before the Disposal Act, the CSA did not address the disposal of controlled substances by ultimate users. To dispose of their controlled substances, ultimate users were permitted to destroy the substances themselves (e.g., mix the substances with coffee grounds, place in a plastic bag, and throw into the garbage or flush) or surrender the substances to law enforcement or DEA. There is concern, however, that throwing controlled substances into the garbage or flushing them can contribute to harming the environment. Because the public has limited options for disposal, outdated and unwanted

⁸ The National Take-Back Days were held on September 25, 2010, April 30, 2011, October 29, 2011, April 28, 2012, and September 29, 2012.

⁹ DEA registrants are not authorized to dispose of controlled substances at these events; DEA registrants must comply with the current DEA regulations regarding disposal of controlled substance stock/inventory.

controlled substances often accumulate in medicine cabinets, easily within reach of children and teenagers. In passing the Disposal Act, Congress recognized that the secure disposal of controlled substances is important because of the significant prescription drug abuse problem in the United States. The Centers for Disease Control and Prevention declared prescription drug overdoses an epidemic.¹⁰ Studies show the adverse consequences associated with the substantially high levels of abuse and misuse (non-medical use) of prescription drugs.

The availability of outdated or unwanted prescription drugs is problematic because there is a concern that young people may perceive prescription and/or over-the-counter drugs as “safer” than illegal drugs because of their intended, legitimate medical use.¹¹ This misperception may be shared by parents. Over 20 percent of parents believe that it is acceptable to give a teen a prescription drug that was not prescribed to them.¹² The 2010 National Survey on Drug Use and Health (NSDUH)¹³ indicates that over 70 percent of Americans twelve and older who used pain relievers non-medically in the previous year obtained the drugs from a friend or relative.¹⁴ Another study found that more than 50 percent of teens obtained prescription drugs from their own family’s

¹⁰ Centers for Disease Control and Prevention, “Morbidity and Mortality Weekly Report,” Vol. 61, No. 1, at 10 (January 13, 2012).

¹¹ Partnership for a Drug-Free America and MetLife Foundation, “2009 Parents and Teens Attitude Tracking Study Report,” March 2, 2010.

¹² Partnership for a Drug-Free America and MetLife Foundation, “2010 Partnership Attitude Tracking Study,” April 6, 2011.

¹³ The National Survey on Drug Use and Health (NSDUH) is an annual survey of the civilian, non-institutionalized, population of the United States aged twelve or older. The survey is conducted by the Department of Health and Human Services Office of Applied Studies, Substance Abuse and Mental Health Services Administration (SAMHSA).

¹⁴ Substance Abuse and Mental Health Services Administration, “Results from the 2010 National Survey on Drug Use and Health: Volume I, Summary of National Findings,” Office of Applied Studies, 2011 (NSDUH Series H-41, HHS Publication No. SMA 11-4658), <http://www.oas.samhsa.gov/NSDUH/2k10NSDUH/2k10Results.pdf>.

medicine cabinet.¹⁵

The prevalence of controlled substance prescription drug abuse among teenagers is right behind their abuse of marijuana (to include organic marijuana and synthetic cannabinoids). The 2011 “Monitoring the Future” survey of teenagers found that 8.1 percent of high school seniors reported non-medical use of Vicodin (a brand name for Schedule III hydrocodone combination products) in the past year, and 4.9 percent reported non-medical use of OxyContin (a brand name for Schedule II oxycodone sustained release products) in the past year.¹⁶ This is consistent with reports by high school students of increased non-medical use of painkillers in the past five years.¹⁷ According to a 2009 survey by the Partnership at Drugfree.org, more than 50 percent of teenagers (grades 9-12) believe that prescription drugs are easier to obtain than illegal drugs.

Prescription drug abuse is the fastest growing drug problem in the United States. Findings from the 2010 NSDUH estimate that 7.0 million persons aged twelve or older used prescription-type psychotherapeutic drugs – pain relievers, anti-anxiety medications, stimulants, and sedatives – non-medically in the previous month.¹⁸ This represents 2.7 percent of the U.S. population.¹⁹ In 2010, 2 million persons aged twelve or older used

¹⁵ Partnership for a Drug-Free America and MetLife Foundation, “2010 Partnership Attitude Tracking Study,” April 6, 2011.

¹⁶ Lloyd D. Johnson, Ph.D., et al, “Monitoring the Future National Results on Adolescent Drug Use: Overview of Key Findings, 2011,” Institute for Social Research, The University of Michigan, 22012.

¹⁷ Lloyd D. Johnston, Ph.D., et al, “Monitoring the Future National Results on Adolescent Drug Use: Overview of Key Findings, 2009,” National Institute of Drug Abuse, 2010 (NIH Publication No. 10-7583).

¹⁸ Substance Abuse and Mental Health Services Administration, “Results from the 2010 National Survey on Drug Use and Health: Volume I, Summary of National Findings,” Office of Applied Studies, 2011 (NSDUH Series H-41, HHS Publication No. SMA 11-4658), <http://www.oas.samhsa.gov/NSDUH/2k10NSDUH/2k10Results.pdf>.

¹⁹ These estimates were similar to those from the 2009 survey but 13 percent higher than those from the 2008 survey.

pain relievers non-medically for the first time.²⁰ On average, every day 2,046 12 to 17-year-olds abuse a prescription pain reliever for the first time.²¹

Non-medical prescription drug use, particularly among young adults, is having a devastating effect on the United States. According to the Centers for Disease Control and Prevention, poisoning deaths, which include drug overdoses such as those from prescription drugs, are the leading cause of injury death in the United States; nearly nine out of ten poisoning deaths are caused by drugs and more than 40% of those involve opioid analgesics.²² According to SAMHSA's latest Drug Abuse Warning Network (DAWN) data, of the 4.6 million emergency department visits in 2009 associated with drug use, about 1.2 million visits involved the non-medical use of pharmaceuticals.²³ Emergency department visits involving non-medical use of pharmaceuticals (misuse or abuse) almost doubled between 2004 and 2009 from 627,291 in 2004 to 1,244,679 visits in 2009 (a 98.4 percent increase).²⁴ About half of the 2009 emergency department visits related to misuse or abuse of pharmaceuticals involved painkillers and more than one-third involved drugs to treat insomnia and anxiety.²⁵

Scope of Proposed Rule

In response to this growing problem, DEA is proposing new, expanded regulations for the disposal of controlled substances by ultimate users in accordance with

²⁰ *Id.*

²¹ Substance Abuse and Mental Health Services Administration, 2010 National Survey on Drug Use and Health.

²² U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, "Drug Poisoning Deaths in the United States, 1980-2008," December 2011.

²³ Behavioral Health Statistics and Quality, "Highlights of the 2009 Drug Abuse Warning Network (DAWN) Findings on Drug-Related Emergency Department Visits," *The DAWN Report*, December 28, 2010.

²⁴ *Id.* at 4.

²⁵ *Id.* at 3.

the Disposal Act. These regulations will provide ultimate users with more options for disposal of their controlled substances so that the controlled substances will not accumulate and be available for misuse, abuse, and accidental ingestion by children and the elderly. In drafting the implementing regulations, DEA considered the public health and safety, ease and cost of program implementation, and participation by various communities. To this end, DEA found that in order to properly address the disposal of controlled substances by ultimate users, it was necessary to conduct a comprehensive review of DEA policies and regulations related to each element of the disposal process, including the transfer, delivery, collection, destruction, return, and recall of controlled substances, by both registrants and non-registrants (e.g., ultimate users).²⁶ The reverse distributor registration category, which is pertinent to the process of registrant disposal, was included in this comprehensive review.

As discussed above, DEA currently regulates the disposal of controlled substances by registrants and other persons in accordance with 21 CFR 1307.21 and regulates the returns process through 21 CFR 1307.12. The existing disposal regulation gives DEA Special Agents in Charge (SACs) the discretion to authorize disposal in a manner that reduces the risk of diversion from this activity on a case-by-case basis. These regulations have changed little since the CSA was enacted. While this approach is effective, with the enactment of the Disposal Act and the increasing need for the responsible disposal of controlled substances by registrants and non-registrants alike, DEA believes that in order to securely and effectively dispose of unwanted or unused controlled substances, consistent nationwide standards on disposal are necessary. As a

²⁶ DEA does not address the proper disposal of listed chemicals by DEA registrants in this rulemaking.

result, DEA proposes to delete 21 CFR 1307.12 on “Distribution to supplier or manufacturer” and 21 CFR 1307.21 on “Disposal of controlled substances” and promulgate a new part 1317 that will expand available disposal options, establish nationwide standards for the disposal of controlled substances, and comprehensively outline the process and procedure for the disposal of controlled substances by registrants, ultimate users, and other non-registrants such as long term care facilities.²⁷

The goal of this proposed new part on disposal, consistent with Congress’s goal in passing the Disposal Act, is to set controlled substance diversion prevention parameters that will allow public and private entities to develop a variety of methods for collecting and destroying controlled substances in a secure, convenient, and responsible manner. DEA believes that the new part on disposal will provide registrants and non-registrants alike clear and consistent requirements for the disposal of controlled substances. It is intended to maximize cost efficiency, voluntary participation, and public accessibility while simultaneously promoting the secure and responsible disposal of controlled substances in order to prevent diversion.

In accordance with the changes described above, DEA proposes to delete any reference to 21 CFR 1307.12 and 1307.21 and replace it with a reference to the new 21 CFR part 1317, where appropriate.²⁸ DEA also proposes to revise 21 CFR

²⁷ Any previous waivers, MOUs, and MOAs issued in accordance with 21 CFR 1307.21 shall be superseded by this rulemaking on the “Disposal of Controlled Substances” if and when it is finalized.

²⁸ DEA proposes in 21 CFR 1301.76 to delete reference to 1307.12 and replace it with reference to 21 CFR part 1317; in 21 CFR 1304.11(e) and the introductory paragraph of 1304.22 to delete reference to 21 CFR 1307.12; in 21 CFR 1301.25(i), 1301.52(c), and 1307.13 to delete reference to 21 CFR 1307.21 and replace it with reference to 21 CFR part 1317; in 21 CFR 1304.25(a)(9) and 1304.25(b)(9) to delete reference to 21 CFR 1307.22 and replace it with reference to 21 CFR part 1317; and in 21 CFR 1304.04(a) to add reference to 21 CFR part 1317. DEA also proposes in 21 CFR 1307.22 to delete reference to 21 CFR 1307.21, and replace it with reference to 21 CFR part 1317. DEA proposes to revise the title of 21 CFR 1307.22 to “Delivery of surrendered and forfeited controlled substances” for clarity.

1301.13(e)(1)(i) to delete reference to a disposer category of registration in the coincident activity column for manufacturers. A disposer category of registration was proposed by DEA in 1995, but was never finalized (60 FR 43732, August 23, 1995). Reference to a disposer category was inadvertently included in a previous rulemaking (68 FR 58587, October 10, 2003).

January 19 – 20, 2011 Public Meeting

On January 19 and 20, 2011, DEA held a well-attended public meeting to receive information from interested parties and the public and gather ideas for drafting regulations for the newly enacted Disposal Act. (The Notice of Meeting was published in the Federal Register on December 22, 2010, 75 FR 80536.) This meeting provided an opportunity for all interested persons — the general public, including ultimate users, parents, pharmacies, waste management companies, long term care and pharmaceutical related industries, as well as federal, state, and local agencies, including law enforcement personnel, and others — to express their views regarding safe and effective methods of disposal of controlled substances consistent with the CSA. Representatives of various industries and organizations as well as federal, state, and local agencies made presentations at the meeting and many submitted written comments prior to the meeting.

In drafting the Disposal Act implementing regulations, DEA gathered information about disposal from the more than 70 written comments and 44 oral presentations that were submitted and transcribed from the two day public meeting. Information and experience resulting from pilot projects around the United States involving mail-back programs, take-back events, and collection receptacles for pharmaceuticals were shared and helped inform this proposed rule. Representatives of law enforcement agencies

provided information on their experience, existing procedures, and perspective, particularly with respect to take-back events as a method of collection. Representatives from DEA registrant and other affected groups, such as pharmacies, reverse distributors, and the waste management industry, provided insights on technology and existing destruction procedures. Presentations by the Environmental Protection Agency, the Food and Drug Administration, the U.S. Postal Service, the U.S. Army, and state and local agencies provided information on relevant federal, state, and local laws and procedures pertaining to the disposal and transportation of controlled substances, particularly pharmaceuticals. DEA appreciated and considered all information provided at or submitted in response to the Notice of Meeting in drafting this NPRM.

Proposed Disposal Act Implementing Regulations

Disposal of Controlled Substances by Ultimate Users – Authorized Persons

In accordance with the Disposal Act, DEA proposes new regulations for the disposal of controlled substances by ultimate users and other non-registrants – in particular: (1) persons lawfully entitled to dispose of ultimate user decedent's property and (2) LTCFs on behalf of ultimate users that reside or have resided at that LTCF. In drafting these proposed implementing regulations, DEA considered the public health and safety, ease and cost of program implementation, and participation by various communities. To this end, DEA proposes three options for ultimate users to dispose of controlled substances: (1) take-back events; (2) mail-back programs; and (3) collection receptacle locations. These proposed options are voluntary and no person is required to establish or operate a disposal program, although any person who chooses to do so and is authorized by DEA to do so must adhere to the final regulations.

DEA proposes to authorize ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property to deliver lawfully possessed controlled substances in Schedules II, III, IV, and V to law enforcement agencies through take-back events, mail-back programs, and collection receptacles, and to authorized collectors through mail-back programs and collection receptacles. DEA is also proposing to authorize LTCFs, on behalf of an ultimate user that resides or has resided at that LTCF, to deliver a resident's lawfully possessed controlled substances in Schedule II, III, IV, or V to certain on-site collection receptacles operated by a registered retail pharmacy that is an authorized collector. The collection of Schedule I controlled substances is not permitted because, generally, ultimate users cannot lawfully possess Schedule I substances unless they are participating in an investigational use of drugs pursuant to 21 U.S.C. 355(i) and 360b(j). For ultimate users in lawful possession of Schedule I substances for investigational use, DEA proposes that they follow the disposal procedures in 21 CFR 1317.85(b). Furthermore, the proposed collection methods are intended for the collection and destruction of lawfully possessed controlled substances, not as an avenue for the disposal of substances that were illegally obtained.

DEA proposes in sections 1317.65 – 1317.80 that controlled substances collected from ultimate users and other authorized non-registrant persons may be comingled with non-controlled substances – both controlled and non-controlled substances may be collected together so long as the requirements outlined for controlled substances are followed. Comingling reduces the risk of diversion and is practical, efficient, and economical. Members of the public cannot easily identify the difference between controlled and non-controlled substances. As collection pilot programs demonstrate, the

requirement that controlled and non-controlled substances be collected separately is expensive, time-consuming, and hampers the collection process. In addition, comingling controlled substances is another way to minimize the risk of diversion of collected controlled substances. For example, many pharmacies and institutional practitioners disperse controlled substances throughout the stock of non-controlled substances in order to deter the theft or diversion of the controlled substances. See 21 CFR 1301.75(b).

DEA proposes in section 1317.30 that federal, state, tribal, and local law enforcement agencies continue with authority to collect ultimate user controlled substances, and that certain registrants authorized by DEA to be a “collector” be authorized to collect controlled substances from ultimate users, persons lawfully entitled to dispose of ultimate user decedent’s property, and, in some circumstances, long term care facilities. DEA is authorizing certain registrant categories to be “collectors” so that DEA can ensure sufficient physical security controls are in place, thereby minimizing the risk of diversion. Registrants are subject to controls related to their DEA registration. These pre-existing controls will protect against the diversion of controlled substances in the process of ultimate user collection.

Possession for Disposal

Once a controlled substance is lawfully dispensed to an ultimate user, the ultimate user is in possession of that substance. Only the ultimate user or other authorized persons (i.e., persons lawfully entitled to dispose of an ultimate user decedent’s property and, in some cases, the LTCF where the ultimate user resides or has resided) may dispose of such controlled substances in accordance with DEA’s proposed ultimate user disposal regulations. In contrast, a controlled substance dispensed for immediate administration

pursuant to an order for medication in an institutional setting remains in the possession of that registered institution, even if the substance is not fully exhausted (e.g., some of the substance remains in a vial, tube, or syringe after administration but cannot or may not be further utilized). Such remaining substance must be properly recorded, stored, and destroyed in accordance with DEA regulations, and all applicable federal, state, tribal, and local laws and regulations. These same principles would apply to hospice settings, which may be registered by DEA as an institutional practitioner or may be unregistered like many LTCFs.

Law Enforcement Agencies

DEA proposes specific language in section 1317.35 to continue to authorize law enforcement agencies, on a voluntary basis, to collect controlled substances from ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property through: (1) take-back events, (2) mail-back programs, and (3) collection receptacles located at the law enforcement agency's physical address.

DEA recommends that law enforcement agencies electing to participate in ultimate user disposal maintain any records of receipt or collection in a manner that is consistent with that agency's recordkeeping requirements for illicit controlled substance evidence handling and store any controlled substances collected in a manner that reasonably prevents the diversion of controlled substances and is consistent with that agency's standard procedures for storing illicit controlled substances. Destruction of controlled substances must be in accordance with applicable federal, state, tribal, and local laws and regulations. DEA recommends that law enforcement agencies also keep a record of any transfer of controlled substances to reverse distributors for destruction; such

records may assist DEA in ensuring that reverse distributors are keeping proper records of those controlled substances they acquire from law enforcement agencies that conduct ultimate user disposal activities. DEA recognizes that law enforcement agencies have existing procedures regarding the handling, storage, or transfer for destruction of controlled substances. These proposed rules do not require changes to those procedures. DEA anticipates that those existing procedures will provide the necessary security to prevent the diversion of controlled substances.

DEA proposes that law enforcement agencies that choose to conduct mail-back programs within their jurisdiction must make available to ultimate users packages described in proposed section 1317.70. Such packages may, however, be made available pursuant to a partnership or other agreement between the law enforcement agency and another person for the purpose of funding, dissemination, production, or other non-collection activity meant to facilitate the law enforcement agency's mail-back program. Such standards will help to alleviate the primary security concerns related to mail-back programs. As explained below, many such concerns exist regardless of the destination of the mail-back packages; thus, security standards related to the mail-back packages must be maintained even if the program is conducted by a law enforcement agency. DEA emphasizes, however, that the authority of law enforcement agencies to conduct ultimate user disposal programs is not a mechanism by which registrants may circumvent these proposed regulations or any other applicable laws or regulations. Any person, group, or entity that partners with a law enforcement agency to implement an ultimate user disposal program must comply with all applicable laws and regulations. In specific terms, any authorized collector that partners with a law enforcement agency to jointly conduct a

collection program must adhere to these proposed regulations and any other applicable laws and regulations.

DEA appreciates that implementing some of the proposed disposal methods may present challenges to some state, tribal, and local law enforcement agencies. When implementing any new community service, all government agencies must balance available resources against established priorities. DEA hopes that these regulations will provide flexibility and opportunities for communities, interest groups, registrants, and law enforcement agencies to partner together to provide cost effective, safe, and convenient methods of ultimate user disposal. DEA looks forward to receiving suggestions from state, tribal, and local law enforcement agencies concerning its proposed regulations for the disposal of controlled substances by law enforcement agencies.

Collectors

DEA proposes in section 1300.01(b) to define a “collector” as a registered manufacturer, distributor, reverse distributor, or retail pharmacy that is authorized to receive a controlled substance for the purpose of destruction from an ultimate user, person lawfully entitled to dispose of an ultimate user decedent’s property, or a long term care facility on behalf of an ultimate user that resides or has resided at that facility. In section 1317.40(a), DEA proposes that registered manufacturers, distributors, reverse distributors, and retail pharmacies may obtain authorization from DEA to be a collector. No manufacturer, distributor, reverse distributor, or retail pharmacy is required to be a collector.

In proposing which DEA registrants could become authorized collectors, DEA

considered public health and safety, diversion control, and convenience and accessibility. In particular, DEA is proposing to authorize registered retail pharmacies to become collectors because such registrants are open to the public and have theft and loss prevention measures within the pharmacy processing area as well as outside the confines of the prescription processing and pick-up area, which easily lends itself to secure collection receptacle placement. Retail pharmacy personnel also routinely handle controlled substances intended for the ultimate user in a public setting while keeping such substances secure, and they have experience comingling controlled and non-controlled substances in the receipt and storage process. As public retail establishments, retail pharmacies generally have experience with the general public as customers and routinely implement theft and loss prevention measures.

For the foregoing reasons, retail pharmacies co-located with hospitals may be authorized to maintain collection receptacles in accordance with these regulations. Registered hospitals themselves, however, may not be authorized as collectors. This should have limited adverse impact on the ability of hospital patients to participate in ultimate user disposal because DEA believes many hospitals are co-located with registered retail pharmacies as a convenient service for outpatients. DEA proposes to restrict hospitals from being authorized collectors because they do not generally operate under the same business model or with similar theft and loss prevention procedures as retail pharmacies. For example, the general public is expected to enter retail pharmacies for short durations in order to conduct retail business. The physical layout of retail pharmacies is designed for open, clearly observable common areas and practically no areas to conceal an unlawful purpose. It would be unusual and suspicious for a person to

spend an extended amount of time in a retail pharmacy without a known, specific purpose, triggering routine theft and loss prevention measures. In contrast, hospitals are generally open 24-hours per day and allow for unsupervised public access; they are much larger than retail pharmacies and many interactions occur behind closed doors without routine theft and loss prevention measures; and foot traffic is not routinely monitored for unlawful purposes. These differences reduce the effectiveness of the proposed regulation's diversion control mechanisms and substantially increase the risk of diversion at hospitals if hospitals were authorized as collectors.

The above discussed risks in allowing hospitals as collectors are not necessary in light of the many other options available to ultimate users to dispose of unwanted or unused controlled substances.

In addition to the increased risk of diversion at hospitals, there is a risk of inadequate recordkeeping if hospitals are permitted as collectors. Unlike retail pharmacies, registered hospitals do not dispense controlled substances to ultimate users pursuant to legitimate prescriptions. Rather, registered hospitals administer controlled substances to inpatients dose by dose, and the controlled substances remain within the possession and control of the registered dispenser, the hospital. As such, registered hospitals may not dispose of controlled substances in collection receptacles, but must follow the revised regulations for registrant destruction, and keep records of such destruction.

DEA is also proposing to allow retail pharmacies to operate collection receptacles in LTCFs under certain circumstances, as discussed below, because—unlike hospitals—LTCFs “face a distinct set of obstacles to the safe disposal of [ultimate user] controlled

substances due to the increased volume of controlled substances they handle.” Pub. L. 111-273, 2, 124 Stat. 2858. DEA is further proposing to authorize registered manufacturers, distributors, and reverse distributors to become collectors because, although such registrants have registered locations that generally are not open to the public, they do have heightened security requirements and are accustomed to receiving, securing, and distributing large amounts of controlled substances on a daily basis. DEA believes that expanding collector authorization to these registrants will provide the necessary convenience and accessibility to the public while ensuring the public health and safety and minimizing potential diversion.

To obtain authorization to be a collector, a manufacturer, distributor, reverse distributor, or retail pharmacy must apply for a modification to their registration in accordance with 21 CFR 1301.51, which DEA is proposing to revise in order to reflect these changes. Upon DEA approval of this modification in registration, each authorized registrant’s DEA Certificate of Registration will specify that registrant’s status as a “collector” and the location(s) approved for collection. Once approved to be a collector, the option for renewal will be available to authorized registrants when they renew their registration.

DEA proposes in section 1317.40(a) that if the registrant that is authorized to collect ceases activities as a collector, such registrant must modify their registration in accordance with 21 CFR 1301.51 to indicate that they no longer collect. In accordance with 21 CFR 1301.52, the registration of any person and any modifications, including authorization to be a collector, terminates if and when such person dies, ceases legal existence, discontinues business or professional practice, or surrenders a registration.

Any registrant that ceases legal existence or discontinues business or professional practice must notify the Administrator promptly of such fact. 21 CFR 1301.52(a). Additionally, a registrant's authorization to collect is dependent upon the registration status of the manufacturer, distributor, reverse distributor, or retail pharmacy. Accordingly, the expiration, revocation, suspension, or surrender of a DEA registration will also result in the loss of the registrant's authorization to be a collector.

DEA proposes in section 1317.40(c) that authorized collectors may conduct the following activities: (1) receive mail-back packages from ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property if the collector has and utilizes an on-site method of destruction; (2) install, manage, and maintain collection receptacles at locations for which the registrant is authorized to collect; and (3) promptly dispose of sealed inner liners and their contents as provided for in § 1317.05(c)(2). DEA proposes in section 1317.40(b) that collection may occur only at the registered locations of manufacturers, distributors, reverse distributors, and retail pharmacies that are authorized to collect at those locations and at long term care facilities (LTCFs) at which registered retail pharmacies are authorized to maintain a collection receptacle (see discussion on LTCFs below).

DEA proposes to authorize as collectors those persons already registered as manufacturers, distributors, reverse distributors, and retail pharmacies because, as registrants, these persons are accountable, have experience handling large volumes of controlled substances on a routine basis, and they are subject to controls related to their DEA registration. These pre-existing controls also protect against the diversion of controlled substances in the process of ultimate user collection. Further, DEA believes

that ultimate user collection should occur at DEA registered locations because these premises are subject to DEA inspection, security, and other controls.²⁹ Such requirements ensure that proper security and other controls are in place to minimize the risk of diversion from the collection of controlled substances. Finally, with the passage of the Disposal Act, Congress did not provide DEA the authority to register persons specifically for the purpose of collecting and disposing of controlled substances from ultimate users. DEA is therefore restricted to operating within its previously existing statutory authority with regard to registration.

In section 1317.45, DEA proposes that authorized collectors employ as an agent or employee with access to or influence over controlled substances acquired pursuant to their status as a collector, only those persons that have never been convicted of any felony offense related to controlled substances and have never, at any time, had an application for registration with DEA denied, had a DEA registration revoked or suspended, or surrendered a DEA registration for cause. DEA is proposing security requirements for collectors in order to strengthen the accountability of the ultimate user collection process, which occurs outside the closed system of distribution, by ensuring that only those employees that have met certain employee screening requirements have access to or influence over controlled substances collected from ultimate users. This requirement is similar to the employee screening requirements for registered practitioners in 21 C.F.R. 1301.76, where there is also a high risk of diversion.

²⁹ In accordance with the Disposal Act, which permitted DEA to, by regulation, authorize LTCFs to dispose of controlled substances on behalf of ultimate users that reside or have resided at the LTCF (see 21 U.S.C. 822(g)(3)), DEA is also proposing to authorize the collection of controlled substances at those LTCFs for which a registered retail pharmacy is authorized to maintain a collection receptacle (see discussion of LTCFs below).

The information that collectors must maintain in their records is proposed in section 1317.50. In accordance with the CSA, every DEA registrant must make a biennial inventory and maintain, on a current basis, a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of. 21 U.S.C. 827(a).³⁰ These records must be maintained separately from all other records of the registrant or, alternatively, in the case of non-narcotic controlled substances, be in such a form that required information is readily retrievable from the ordinary business records of the registrant. 21 U.S.C. 827(b)(2). The records must be kept and be available for at least two years for inspection and copying by officers or employees of the Attorney General. 21 U.S.C. 827(b)(3). DEA may promulgate regulations that specify the information that registrants are required to maintain in their records. 21 U.S.C. 827(b).

To this end, DEA is proposing information that collectors must record based on the particular ultimate user collection method utilized (i.e., mail-back program or collection receptacle). The inner liners and mail-back packages that DEA proposes to be utilized in the collection of ultimate user controlled substances are intended for the disposal of controlled substances. As a result, DEA is requiring that collectors make an inventory of all inner liners and mail-back packages and maintain records on the use and destruction of such liners and packages in order to properly account for the disposal of controlled substances in accordance with the CSA. Once sealed, inner liners and mail-

³⁰ The recordkeeping requirements differ depending on whether the records pertain to the registrant's inventory or stock, or the registrant's activities as an authorized collector. The requirements contained in the current regulations are those imposed on registrants with regard to their stock on hand (i.e., their inventory of controlled substances). Controlled substances collected from ultimate users are not part of a registrant's inventory and would not be counted as such.

back packages shall not be opened, x-rayed, or otherwise penetrated and the substances contained in the inner liners and mail-back packages may not be individually handled, counted, inventoried, or otherwise discerned.

DEA is also proposing in section 1317.50 that collectors be exempt from the ARCOS requirements in 21 CFR 1304.33 and the order form requirements in 21 CFR part 1305 only when they collect controlled substances from ultimate users or other authorized non-registrant persons. Such substances are outside the closed system of distribution, and these tracking and accountability mechanisms are designed for substances within the closed system of distribution.

Registered Reverse Distributors and Distributors

DEA appreciates that law enforcement agencies and authorized collectors may not have the resources to destroy controlled substances received from ultimate users. Such persons may use the services of a registered reverse distributor for this purpose. DEA proposes in section 1317.55(a) to authorize registered reverse distributors to acquire for purposes of destruction controlled substances that have been collected by: (1) law enforcement agencies; and (2) authorized collectors through collection receptacles. DEA also proposes in section 1317.55(b) to authorize registered distributors, in addition to registered reverse distributors, to acquire for purposes of destruction controlled substances collected by authorized collectors through collection receptacles.³¹ DEA is proposing in section 1317.55(c) that registered reverse distributors and registered distributors that choose to acquire such collected controlled substances from authorized

³¹ Reverse distributors or distributors may acquire controlled substances that have been collected by collection receptacle at either an authorized collector's registered location or, pursuant to sections 1317.75(g) and 1317.80(d), at a long term care facility for which a registered retail pharmacy is authorized to collect. See subsequent discussion for more detail on reverse distributors.

collectors do so in the manner prescribed for acquiring registrants' controlled substance inventory for purposes of disposal. This consistent procedure will help provide certainty in the disposal process, and help prevent errors during the acquisition process. Such acquisitions may be made pursuant to pick-up by the reverse distributor or distributor at the registrant's registered or authorized collection location, by delivery by common or contract carrier to the reverse distributor's or distributor's registered location, or by direct delivery from a non-practitioner to the reverse distributor's or distributor's registered location.

DEA proposes that authorized collectors that conduct mail-back programs must have and use an on-site method of destruction, and, as a result, these collectors will not be authorized to deliver or transfer those substances to a registered reverse distributor or distributor. The requirement to destroy on-site would not apply to law enforcement agencies that conduct mail-back programs; law enforcement agencies may continue to transfer any collected substance to an authorized reverse distributor.

Registered reverse distributors and distributors do not have to be authorized collectors to acquire collected controlled substances from law enforcement agencies or authorized collectors. In such circumstances, the substances being acquired have already been collected by law enforcement agencies and authorized collectors and should already be securely sealed in an inner liner or mail-back package in accordance with sections 1317.65 – 1317.80.

DEA also proposes in section 1317.55(c) that those registered reverse distributors and distributors that acquire controlled substances from law enforcement agencies and authorized collectors must destroy such controlled substances or securely transfer and

store the controlled substances utilizing applicable procedures described in section 1317.15(c) until timely destruction can occur. In addition, reverse distributors and distributors must destroy the controlled substances as soon as practicable but no later than fourteen calendar days of pick-up or delivery, pursuant to proposed section 1317.15(d). Consistent procedures for the acquisition and disposal of registrant inventory and ultimate user collected controlled substances will streamline practices and help prevent confusion and error in the transfer, storage, and destruction processes. Any storage of such substances at the registered location of the reverse distributor or distributor must be in a manner consistent with the security requirements for Schedule II controlled substances. This is to minimize the risk of diversion because inner liners and mail-back packages shall not be opened once they are sealed and their contents will not be known, and, as a result, such liners and packages should be stored as though each contains a Schedule II controlled substance.

DEA also proposes in sections 1317.55(d) and 1317.100 to require that these reverse distributors and distributors keep records regarding the receipt, storage, transfer, and destruction of those controlled substances acquired from law enforcement agencies and authorized collectors.³² Such records will help to ensure that the collected substances are accounted for and properly destroyed.

Finally, DEA proposes in section 1317.55(e) and (f) to exempt reverse distributors and distributors that acquire collected controlled substances from law enforcement agencies or authorized collectors from the ARCOS requirements in 21 CFR 1304.33 and the order form requirements in 21 CFR part 1305, only when they acquire

³² For clarity, DEA proposes in 21 CFR 1304.11(e)(2) and 1304.22(b) to cross reference these reverse distributor and distributor recordkeeping requirements covered by 21 CFR 1317.55.

controlled substances that have been collected from ultimate users by law enforcement agencies or authorized collectors. . Such substances are outside the closed system of distribution, and these tracking and accountability mechanisms are designed for substances within the closed system of distribution.

Disposal of Controlled Substances by Ultimate Users – Authorized Methods

Take-Back Events

The first method of collection that DEA proposes, in section 1317.65, is take-back events. Ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property would be authorized to utilize a take-back event in accordance with 1317.65 to dispose of their controlled substances in Schedules II, III, IV, and V. As mentioned above, DEA is proposing specific language that will continue to authorize law enforcement agencies to conduct take-back events. DEA believes that take-back events should be conducted only by law enforcement agencies because such events are highly publicized, are often held at easily accessible locations within a community, and do not have the same security controls as permanent collection locations. As such, take-back events are more vulnerable to diversion. Although only law enforcement agencies would continue to be authorized to conduct take-back events, DEA proposes in section 1317.65(a) that private entities or community groups may continue to partner with law enforcement to hold community take-back events, thereby allowing for greater community involvement, education, and outreach, while minimizing the risk of diversion.

Many of the provisions that DEA proposes in section 1317.65, with respect to take-back events, are recommendations ("should" instead of "shall") because DEA has no intent to change existing law enforcement procedures regarding the handling, storage,

transfer, or destruction of controlled substances. DEA is, however, proposing some requirements that law enforcement agencies must follow in order to hold a take-back event. For example, in section 1317.65(b), DEA proposes that any law enforcement agency that conducts a take-back event shall appoint a law enforcement officer, who must be employed full time by the agency, to oversee the collection. Further, law enforcement officers employed³³ and authorized by the law enforcement agency conducting the take-back event must maintain control and custody of the collected substances from the time the substances are collected from the ultimate user or person authorized to dispose of the ultimate user decedent's property until secure transfer or destruction has occurred. DEA believes that designated law enforcement officers should be required to maintain control and custody of the controlled substances at all times in order to protect against theft and diversion.

Take-back events provide ultimate users the opportunity to dispose of Schedule II, III, IV, and V controlled substances, which they legally possess, at a designated place and time. DEA proposes in section 1317.65(c) that each take-back event should have at least one receptacle for the collection of permitted substances. Although this is only a recommendation for law enforcement agencies that conduct take-back events, DEA believes that optimal security and protection of public health and safety can be achieved if controlled and non-controlled substances are collected in a collection receptacle that is

³³ DEA proposes in section 1317.02 to define "law enforcement officer" for the purpose of 21 CFR part 1317. In order to prevent the appearance that a third party has access to or influence over controlled substances, for example by directly or indirectly funding law enforcement disposal activities, DEA is requiring the law enforcement officer to be directly employed full time by a law enforcement agency, be under the direction and control of the federal, state, tribal, or local government, be acting in the course of their official duty, and be duly sworn and given the authority by the federal, state, tribal, or local government to: (1) carry firearms; (2) execute and serve warrants; (3) make arrests without warrant; and (4) make seizures of property.

securely locked and substantially constructed with an outer shell and removable inner liner.

DEA also proposes in section 1317.65(e) that only an ultimate user or person lawfully entitled to dispose of an ultimate user decedent's property may transfer controlled substances to the law enforcement agency during the take-back event. No other person, such as a take-back event volunteer, may handle or touch the controlled substances at any time. DEA is proposing this requirement to limit the number of hands through which the substances pass because the risk of diversion increases each time a controlled substance is transferred to a new person.

Mail-Back Programs

The second method of collection that DEA proposes, in section 1317.70, is mail-back programs. Ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property are authorized to utilize a mail-back program in accordance with 1317.70 to dispose of their controlled substances in Schedules II, III, IV, and V. DEA proposes in section 1317.70(a) specific language to continue to authorize law enforcement agencies to voluntarily conduct mail-back programs; and mail-back programs may be conducted by registered manufacturers, distributors, reverse distributors, or retail pharmacies that: (1) are authorized as collectors; and (2) have and utilize an on-site method of destruction at their registered location. The security requirements proposed with respect to the other proposed collection methods (take-back events and collection receptacles) are adequate to ensure that controlled substances are collected and maintained in a manner that prevents diversion until transfer and destruction can occur. Designing regulations that ensure the security of controlled

substances in the context of mail-back programs is challenging because, unlike take-back events and collection receptacle locations, there is a third party who handles the controlled substances as they are transferred from the ultimate user to the authorized collector in mail-back programs – the mail system. This unique circumstance provides opportunities for diversion that do not exist with the other collection methods, thus requiring more stringent controls than the other methods. As a result, DEA proposes to allow mail-back programs to be voluntarily conducted by DEA registrants that are authorized collectors that have and utilize an on-site method of destruction and by law enforcement agencies in order to minimize the transfer of controlled substances between various locations. This is intended to minimize the risk of diversion.

DEA also proposes in section 1317.70(c) that any authorized collector or law enforcement agency that conducts a mail-back program must produce and provide specified packages, either at no cost or for a fee, to ultimate users for the collection of controlled substances through the mail, and may do so in partnership with third parties for convenience, funding, or any other lawful purpose. One example of such a partnership would be when an authorized collector with an on-site method of destruction (e.g., a DEA-registered reverse distributor) produces appropriate mail-back packages, and allows a third party business partner that is frequently accessed by the public (e.g., a retail pharmacy) to provide these packages to patronizing customers. In this circumstance, the registered reverse distributor would be responsible for operating the mail-back program, including recordkeeping and security, and it must receive the mail-back packages directly at its registered location for on-site destruction. DEA proposes that packages used for collection by mail-back must meet certain specifications. The proposed package

requirements include only those specifications necessary to ensure that controlled substances sent through the mail, outside of the closed system of distribution, can be tracked with a high degree of confidence in their security. These requirements are intended to protect public health and safety and prevent the diversion of controlled substances.

In particular, the packages are proposed to be postage paid (e.g., business reply), preaddressed to the authorized mail-back location, nondescript, tamper-evident and tear-resistant, among other things. This is to ensure that the mailers are not delayed or diverted through address changes, theft, or because the package has inadequate postage. Such mailers must be addressed to the authorized collector's registered location with the on-site method of destruction or to the law enforcement agency's physical address and cannot be addressed to any other location, such as a post office box.

DEA is also proposing to require that each package must have a unique identification number so that each package can be tracked. In an effort to increase the ease of program implementation and to enhance the security of the mail-back option, DEA is also proposing that each package include instructions for the user that indicate the process for mailing back the package, the permitted substances that can be sent, and notice that only packages provided by the authorized collector will be accepted for destruction.

DEA considered requiring registrants to establish a system that would allow ultimate users to notify the collector when the ultimate user mailed back a package containing controlled substances, similar to pilot projects described in the public hearing. However, the burden of requiring a notification system outweighed the benefits of such a

system, particularly when other security-enhancing measures are proposed. DEA believes that the collector inventory and recordkeeping requirements – that a collector conducting a mail-back program must keep inventory of mailers created and record the unique identification number of each mail-back package received – coupled with the stringent package specifications – for example the package must be postage paid and preaddressed – are sufficient controls to help protect against diversion while minimizing the burden on ultimate users. However, while DEA is not proposing to require collectors to create and maintain a notification system, such a system is not prohibited by the proposed regulations. To ensure privacy, the proposed language of section 1317.70(d) specifies that the public cannot be required to provide any personally identifiable information when mailing back controlled substances to an authorized collector.

DEA proposes in section 1317.70(e) that the authorized collector shall accept for the purpose of on-site destruction only those packages that they made available, directly or in partnership with a third party, for the collection of controlled substances. This requirement is designed so that authorized collectors, who control the production of uniform mail-back packages that are both nondescript and not readily identified as containing controlled substances, can easily identify authorized packages and thereby increase the likelihood that they accept only those packages that they are authorized to accept.

If the authorized collector inadvertently and unknowingly accepts controlled substances from an ultimate user in a package that they did not make available for the collection of controlled substances, the authorized collector shall notify the DEA office in their area of the receipt of the package within three business days of receipt and store the

package, in a manner consistent with the routine mail-back package storage requirements discussed below, until the collector receives further instructions from DEA.

The “three business day” requirement allows the registrant enough time to process the packages received while still ensuring that DEA is notified of the incident in a timely manner thus allowing further investigation if necessary. The requirements for postage paid and preaddressed packages are designed to reduce the likelihood that authorized collectors will receive unauthorized controlled substances via mail-back programs because the sender would have to address such package and pay for postage. Ultimate users will likely not engage in such inconveniences when postage paid and preaddressed mailers are available.

DEA proposes in section 1317.70(f) that law enforcement officers employed by the law enforcement agency and “authorized employees” of a collector be the only individuals permitted to handle packages collected through a mail-back program. Under the proposed definition in 1317.02(a), an “authorized employee” is a person directly employed by the registrant full time (i.e., not employed as a contractor or agent of a third party) and must not have been convicted of any felony offense related to controlled substances and not have had at any time an application for registration with DEA denied, had a DEA registration revoked or suspended, or surrendered a DEA registration for cause. These enhanced security requirements are proposed consistent with existing security screening procedures for employees of certain registrants and will strengthen the integrity of the mail-back process by ensuring that only trusted employees have access to or influence over controlled substances.

DEA proposes in section 1317.70(f) that upon receipt of a package through a

mail-back program, an authorized collector shall not open the package, x-ray, analyze, or otherwise penetrate the package. DEA proposes in section 1317.05(c)(1) that the authorized collector must promptly destroy the package on-site or securely store the package until prompt on-site destruction or timely notification to DEA of receipt of an unauthorized package in accordance with 1317.70(e) can occur. DEA is proposing the flexible “prompt” destruction and secure storage standard for collectors rather than a specific time frame to ensure that controlled substances do not accumulate while pending destruction or secure storage and are destroyed in a prompt manner, thus reducing the opportunities for diversion, while still accounting for the individual circumstances of registrants that destroy controlled substances. If the authorized collector is a reverse distributor, however, such destruction must occur as soon as practicable but no later than fourteen calendar days of receipt in accordance with proposed section 1317.15(d), which is discussed below.

Mail-back programs provide a convenient means of disposal for ultimate users who may not otherwise have access to a safe method of disposal. Mail-back programs are valuable because they may be made available to a large number of ultimate users regardless of geographic location. Because this method of ultimate user disposal presents high risks of diversion, DEA has carefully weighed many options and proposes the outlined requirements. The proposed requirements may limit the number of persons authorized to conduct a mail-back program; however, a single authorized mail-back program is capable of receiving packages from any location within the U.S.³⁴ The mail-

³⁴ Mail-back programs are restricted to the receipt of mailers initiated within the U.S. in order to be consistent with the import requirements of the CSA as provided in Subchapter II of Chapter 13 of Title 21 of the U.S. Code (21 U.S.C. 951 et. seq.).

back method of disposal for ultimate users is a valuable and convenient option, however, the high risk of diversion inherent to this method requires stringent controls, including post-collection tracking and accountability mechanisms, as well as on-site destruction by authorized collectors.

Collection Receptacles

The third voluntary method of collection that DEA proposes, in section 1317.75, is collection receptacles. DEA proposes specific language in section 1317.75(a) to continue authorization for any federal, state, tribal, or local law enforcement agency to maintain a collection receptacle at the law enforcement agency's physical location as well as to authorize any DEA registered manufacturer, distributor, reverse distributor, or retail pharmacy authorized as a collector to maintain a collection receptacle at their DEA registered location. Collection receptacles may be located at a collector's registered location (and certain authorized LTCFs, as discussed below) or at a law enforcement agency's physical location – they may not be placed at non-registered locations such as libraries or community centers. DEA is proposing collection receptacles be placed at registered locations to ensure that controlled substances are collected at those locations that have existing security controls in place, with the exception of LTCFs, thereby reducing the risk of diversion while still providing for a convenient option for ultimate user disposal.

Like take-back events and mail-back programs, DEA proposes in sections 1317.75(b) and (c) and 1317.80(a) that the only persons that may transfer controlled substances to the authorized collector's collection receptacle are the ultimate user, persons lawfully entitled to dispose of an ultimate user decedent's property, and, as

discussed below, a LTCF on behalf of an ultimate user that resides or has resided at that LTCF when a collection receptacle is located at that LTCF. This requirement is proposed in order to limit the number of hands through which the substance passes because the risk of diversion increases each time a controlled substance is transferred to a new person.

The proposed collection receptacle requirements in section 1317.75(d) and (e) are intended to protect against diversion. In particular, DEA is proposing the minimum collection receptacle requirements necessary to protect against diversion while allowing flexibility. The collection receptacles used by authorized collectors must have a permanent outer container with a removable inner liner. The outer container must have an opening big enough to allow contents to be added to the inner liner, but small enough to prevent removal of the inner liner contents. The opening must be capable of being locked at times when an authorized employee is not present, unless the collection receptacle is located in a secured area of a long term care facility which is regularly monitored by LTCF personnel.

DEA defines an inner liner in section 1317.02 and proposes requirements for inner liners in section 1317.60. In particular, like the mail-back packages, the inner liner must be waterproof, tamper-evident, and tear-resistant. The inner liner must be removable and sealable immediately upon removal without emptying or touching the contents and the contents of the inner liner shall not be viewable from the outside when sealed. The size of the inner liner must be clearly marked on the outside of the liner, for example, be clearly marked “5 gallon” or “10 gallon.” Finally, the inner liner must bear a permanent, unique identification number that enables the liner to be tracked. DEA is proposing these inner liner requirements to ensure that controlled substances are collected

and destroyed in an accountable, secure, and convenient way in order to both prevent the diversion of controlled substances and to protect public health and safety.

In an effort to increase the ease of program implementation, to increase the security of collection by collection receptacle and to remind the public that illicit substances shall not be collected, DEA is also proposing that the outer container prominently display a sign indicating that only non-controlled drugs and Schedule II, III, IV, or V controlled substances are acceptable for collection. DEA seeks comment on the value and utility of requiring that a specific, uniform symbol be placed on each collection receptacle.

DEA is also proposing other security measures, including the requirement that collection receptacles be securely fastened to a permanent structure such as a wall, floor, or immovable countertop so that they cannot be removed. At a registered location, the collection receptacle must be located within the immediate proximity of a designated area where controlled substances are stored and where an authorized employee is present. At a long term care facility, the collection receptacle must be located in a secured area monitored by personnel of that long term care facility. In addition, access to the inner liner is restricted to authorized employees. Containers secured in compliance with the proposed requirements are intended to deter and prevent theft and pilferage.

DEA proposes in section 1317.75(g) that the removal of the inner liner of the collection receptacle shall be performed by or under the supervision of at least two authorized employees of the authorized collector. To this end, a registered reverse distributor or distributor is permitted to remove and take the inner liner of the collection receptacle for destruction so long as the removal is performed under the supervision of at

least two authorized employees of the authorized collector. In accordance with section 1317.05(c)(2), upon removal of the inner liner of the collection receptacle, the authorized collector shall promptly: (1) destroy the inner liner and its contents; or (2) store the inner liner and its contents at the collector's registered location in a manner consistent with the security requirements for Schedule II controlled substances until prompt destruction can occur.

Authorized collectors who are registered practitioners³⁵ shall dispose of the sealed inner liners and their contents in one of the following ways: (1) promptly destroy the sealed inner liners and their contents, using an on-site method of destruction in accordance with Subpart C of part 1317 of this chapter; (2) promptly deliver the sealed inner liners and their contents by common or contract carrier to the registered location of a reverse distributor or distributor for destruction, or by reverse distributor pick-up at the collector's registered or authorized location; or (3) request assistance from the Special Agent in Charge of the Administration in the area in which the practitioner is located by submitting one copy of DEA Form 41 identifying what is to be disposed.

Authorized collectors who are not registered practitioners³⁶ shall dispose of the sealed inner liners and their contents in one of the following ways: (1) promptly destroy the sealed inner liners and their contents, using an on-site method of destruction in accordance with Subpart C of part 1317 of this chapter; (2) promptly deliver the sealed inner liners and their contents by common or contract carrier to the registered location of

³⁵ The basis for distinguishing between practitioners and non-practitioners when specifying disposal procedures is explained in detail below under the discussion of controlled substance inventory disposal, beginning on page 61.

³⁶ The basis for distinguishing between practitioners and non-practitioners when specifying disposal procedures is explained in detail below under the discussion of controlled substance inventory disposal, beginning on page 61.

a reverse distributor or distributor, or by reverse distributor pick-up at the collector's registered or authorized location; or (3) promptly transport the sealed inner liners and their contents by the collector's own means to the registered location of a reverse distributor or distributor, or to the location of destruction. DEA is proposing the flexible "prompt" destruction, transfer, and storage standard for collectors rather than a specific time frame to ensure that controlled substances do not accumulate while pending destruction, transfer, or storage, while still accounting for the individual circumstances of registrants that operate and maintain collection receptacles. If the authorized collector is a reverse distributor, however, such destruction must occur as soon as practicable but no later than fourteen calendar days of receipt in accordance with proposed section 1317.15(d), which is discussed below.

Long Term Care Facilities

The Disposal Act authorized the Attorney General to develop regulations to permit long term care facilities to dispose of controlled substances on behalf of ultimate users who reside or have resided at such facilities in a manner that provides effective controls against diversion and is consistent with public health and safety. As such, DEA proposes in section 1317.80 to allow collection receptacles to be placed at long term care facilities for the disposal of controlled substances in accordance with outlined requirements.

DEA is proposing that only a registered retail pharmacy that receives authorization to collect at a specific long term care facility may manage and maintain collection receptacles at that long term care facility and remove or supervise the removal of the inner liner of the collection receptacles at that long term care facility. Such

registered retail pharmacies that desire to operate a collection receptacle at a long term care facility must apply to modify their registration in accordance with 21 CFR 1301.51 and include in their application for modification in registration the physical location of each long term care facility at which the registered pharmacy intends to operate a collection receptacle. If the retail pharmacy that is authorized to collect ceases activities as a collector, such registrant must modify their registration in accordance with 21 CFR 1301.51 to indicate that they no longer collect or have ceased collection at a particular physical location.³⁷ The requirements in 21 CFR 1301.52(a) related to the termination of registration also apply.

A registered retail pharmacy authorized to maintain a collection receptacle at a long term care facility shall comply with the proposed requirements in 21 CFR 1317.75 that govern collection receptacles. At a long term care facility, the collection receptacle must be located in a secured area monitored by personnel of that long term care facility. In addition, access to the inner liner is restricted to authorized employees of the registered retail pharmacy. Because an authorized employee must be employed full time by the registrant, employees of the long term care facility will not have access to the inner liner of the collection receptacle, unless they are also a full time employee of the registered retail pharmacy that maintains that collection receptacle. In addition, DEA is proposing that two authorized employees of the retail pharmacy must remove or supervise the removal of the inner liner from the collection receptacle. In an effort to increase security and control of controlled substances collected, no employee of the long term care facility

³⁷ For the purposes of 21 U.S.C. 880(a), collection receptacles at long term care facilities maintained by a registered retail pharmacy authorized as a collector is a “controlled premise” of that registered retail pharmacy.

will have access to or influence over the contents of the collection receptacle, except to deposit controlled substances into it.

DEA is proposing that long term care facilities be permitted to dispose of controlled substances in Schedules II through V on behalf of an ultimate user who resides or has resided at such long term care facility. As with all other collection methods, controlled and non-controlled substances may be comingled in the collection receptacle. DEA proposes that the long term care facility be required to transfer controlled substances into collection receptacles (on behalf of ultimate users who reside or have resided at the long term care facility) immediately, but no longer than three business days after it is determined that the ultimate user no longer needs or wants, or should discontinue use of the controlled substance. DEA proposes this requirement on the transfer of controlled substances at a long term care facility in an effort to prevent the accumulation of ultimate user controlled substances at long term care facilities. DEA believes that this requirement balances security concerns with the ease of long term care facility participation by allowing these facilities to determine whether it is appropriate for them to dispose on behalf of an ultimate user.

Pursuant to 21 U.S.C. 822(g)(3), DEA is proposing that a long term care facility must dispose of those controlled substances only by depositing the substances into an authorized collection receptacle at the long term care facility. The long term care facility is not permitted to deliver or transfer the controlled substances off-site. If the long term care facility does not have access to an on-site collection receptacle, they are not otherwise permitted to dispose of a controlled substance on behalf of an ultimate user. Rather, the ultimate user or persons lawfully entitled to dispose of ultimate user

decedent's property should dispose of those controlled substances. See 21 U.S.C. 822(g)(1) and 822(g)(4).

Because ultimate user medications are concentrated in and often administered by long term care facilities, DEA considered proposing to authorize long term care facilities to dispose of controlled substances on behalf of an ultimate user through mail-back programs and through take-back events. However, the majority of such facilities are not registered by DEA to handle controlled substances, and, therefore, do not have in place physical security controls and other requirements that minimize the risk of diversion such as the obligation to maintain effective controls against diversion, report thefts and losses, and screen certain employees for controlled substance-related felony convictions. DEA believes that only authorized DEA registrants and law enforcement agencies should be authorized to collect controlled substances from ultimate users because they have in place the proper security and other controls to help guard against diversion. Because long term care facilities are typically not registered with DEA and face the unique challenge of disposing of controlled substances on behalf of an ultimate user, DEA is proposing an option for LTCFs that balances convenience with security.

The on-site collection receptacles will reduce the risk that controlled substances may be removed from the facilities by employees (e.g., to transport substances to a take-back event for disposal) who will not be subject to the same screening procedures as employees of authorized collectors, such as the requirement that authorized employees who have access to or influence over controlled substances have no felony convictions related to controlled substances. Additionally, DEA believes that the mail-back option is not suitable because of the likelihood that long term care facilities may need to dispose of

large quantities of controlled substances or dispose of controlled substances on a frequent basis. One security aspect of the mail-back method of disposal is the requirement that mailers be non-descript, so as not to be readily identifiable as containing controlled substances. If a large number of such mailers are consistently sent from an unregistered facility whose residents are likely to possess controlled substances, such as a long term care facility, that security measure loses much of its efficacy, thereby increasing the risk of diversion, and may even have the unintended effect of making a long term care facility's mailing system a target for diversion.³⁸ DEA is, therefore, proposing to only permit long term care facilities to use an on-site collection receptacle that is under the control of an authorized retail pharmacy registrant to dispose of controlled substances on behalf of an ultimate user. DEA believes that a secure on-site collection receptacle is the best method to protect against diversion and is consistent with public health and safety.

Although LTCFs may only dispose of their residents' controlled substances through collection receptacles at the LTCF, LTCF residents themselves may utilize any other disposal method available to ultimate users, including mail-back programs and take-back events. Care should be taken to ensure that LTCF residents' use of mail-back programs and take-back events does not result in the accumulation of controlled substances in a single location susceptible to internal or external diversion threats, as discussed above.

Additional Security Controls for the Collection of Controlled Substances through Mail-

³⁸ Although reverse distributors and other collectors conducting mail-back programs will likewise receive a large number of mailers, DEA does not anticipate that the same risk exists. Collectors authorized to conduct mail-back programs will be DEA registrants that already routinely receive controlled substances and have in place security controls. A long term care facility, however, is likely not a DEA registrant, does not already routinely send out controlled substances, and will not have in place the same types of security controls.

Back Programs and Collection Receptacles

As discussed above, sealed mail-back packages and inner liners acquired by collectors and registered reverse distributors and distributors must be stored in a manner consistent with the physical security requirements for Schedule II controlled substances. Registered reverse distributors, distributors, and manufacturers authorized as collectors and that store mail-back packages and inner liners acquired from an ultimate user must follow the physical security controls for storing Schedule II controlled substances in accordance with 21 CFR 1301.72, which DEA proposes to revise. An authorized collector that is a retail pharmacy must follow the physical security controls for storing Schedule II controlled substances in accordance with 21 CFR 1301.75; however, such sealed mail-back packages and inner liners may not be dispersed through the practitioner's stock of non-controlled substances as described in 21 CFR 1301.75(b), which DEA proposes to revise. DEA understands that storing sealed mail-back packages and inner liners as though they are Schedule II controlled substances is a stringent requirement; however the majority of authorized collectors, as registrants, are likely to already have these storage capabilities in place. DEA is proposing these physical security requirements because Schedule II is the highest schedule of controlled substances that is lawfully permitted to be included in the mail-back packages and inner liners. Because mail-back packages and inner liners may not be opened and their contents will not be known, such packages and liners should be stored as though each package and liner contains a Schedule II controlled substance.

In the event of theft, pilferage, or loss, registrants must notify DEA, in accordance with 21 CFR 1301.76(b) and 1301.74(c). DEA considers any theft or loss from a

collection receptacle or mail-back program to be a “significant loss” within the meaning of the regulation because such losses would be attributable to the unique activities involving the disposal of controlled substances. 21 CFR 1301.74(c)(3). Also, because the controlled substances collected cannot be individually handled or sorted, it must be assumed that the loss includes Schedule II controlled substances. 21 CFR 1301.74(c)(2) and 1301.76(b). Finally, collection receptacles and mail-back packages are likely candidates for diversion because these collection methods are highly publicized and accessible to the public, and, as a result, any theft or loss from these collection methods is considered significant. 21 CFR 1301.74(c)(5) and 1301.76(b)(5).

Tracking Controlled Substances Collected from Ultimate Users and Other Authorized Non-registrants from Collection to Destruction

In accordance with the closed system and the statutory framework of the CSA, DEA must ensure that all controlled substances collected from ultimate users are properly and promptly secured, stored, and destroyed. DEA considered allowing authorized persons to count or otherwise inventory controlled substances collected from ultimate users. Any effort to count, identify, or otherwise inventory the contents of sealed packages or inner liners, however, would require individualized identification of the contents, increase the number of hands through which controlled substances pass, and require that the packages and inner liners remain opened and exposed for extended periods of time. These factors greatly increase the risk of diversion and, when combined with the increased costs associated with such efforts, outweigh the potential benefit.

As a result of these security and diversion prevention considerations, DEA is proposing a system of collection that requires the ultimate user or other authorized non-

registrant person in lawful possession of a controlled substance to personally handle such substance at all times until it is safely and securely placed in an authorized mail-back package or in an appropriate collection receptacle at an authorized location or at a take-back event. Additionally, an authorized collector would be required to collect items only in a collection receptacle with an inner liner or in a mail-back package, both of which must be uniquely identifiable, sealable, waterproof, tamper-evident, and tear-resistant. No person may open or otherwise access any secured mail-back package or inner liner.

DEA is proposing that each inner liner and mail-back package provided by an authorized collector must have a unique identification number that enables the liner and package to be tracked. The authorized collector must record the unique identification number located on the inner liner or mail-back package so that it can be properly tracked from collection to destruction. Law enforcement agencies are encouraged, but not required, to implement similar recordkeeping and tracking procedures. DEA believes that the proposed recordkeeping and tracking system is the most effective and efficient way to ensure that those controlled substances collected from ultimate users and other authorized non-registrants are secure until destruction, and are actually destroyed. DEA has proposed a rule that allows authorized collectors the flexibility to create a tracking system that is proportionate to the scope and method of their desired disposal program while also meeting the applicable security and control requirements proposed by DEA.

Disposal of Controlled Substances by Registrants

The procedures for the disposal of controlled substances by registrants are often determined on a case-by-case basis by the DEA Special Agent in Charge (SAC) in the area where the registrant is located. In many circumstances, the SAC has the discretion

to determine how to authorize and instruct registrants to dispose of controlled substances, including how the substances may be destroyed. 21 CFR 1307.21(a) and (b).

DEA proposes to expand the inventory³⁹ disposal options available to registrants, delete the existing rule related to registrant disposal (21 CFR 1307.21), and incorporate similar requirements on proper disposal procedure, security, and recordkeeping into a new part 1317 on disposal. DEA is proposing these changes to ensure consistency in disposal procedures among registrant categories, regardless of geographic location. Such regulations will reduce the burden on registrants by eliminating the existing requirement for every registrant to contact the SAC in their area when they wish to destroy controlled substances. Also, the procedures and security and recordkeeping requirements that DEA proposes are intended to codify existing practice and to set singular and consistent procedures for DEA registrants in accordance with their authorized business activities while protecting the public health and safety and minimizing the risk of diversion.

Registration requirements and authorized activities vary depending on the type of controlled substance business activity in which a person is engaged. Accordingly, if a registrant desires to deliver controlled substances for any lawful purpose, the registrant must be authorized by his registration to conduct the delivery—the registrant must be authorized to engage in such conduct either as a business activity or coincident activity. This general rule also applies if a registrant desires to deliver controlled substances to an authorized person by transporting the substances itself and maintaining custody and control of the substances during transportation.

³⁹ “Inventory” means “all factory and branch stocks in finished form of a basic class of controlled substance manufactured or otherwise acquired by a registrant, whether in bulk, commercial containers, or contained in pharmaceutical preparations in the possession of the registrant (including stocks held by the registrant under separate registration as a manufacturer, importer, exporter, or distributor).” 21 CFR 1300.01(b).

Pursuant to the Controlled Substances Act, registration to distribute conveys broad authority to deliver controlled substances for a lawful purpose. “Distribute” means to “deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term ‘distributor’ means a person who so delivers a controlled substance or listed chemical.” 21 U.S.C. 802(11). Accordingly, registrants authorized to distribute controlled substances (e.g., non-practitioners such as manufacturers, distributors, and reverse distributors) may themselves deliver such substances to authorized persons for the purpose of disposal in accordance with applicable security and recordkeeping procedures. In contrast, the Controlled Substances Act narrows the authorization of practitioners⁴⁰ (e.g., physicians, pharmacies, and hospitals) to “dispense,” which means “to deliver a controlled substance *to an ultimate user* or research subject by, or *pursuant to the lawful order of, a practitioner, including the prescribing and administering of a substance . . .*” 21 U.S.C. 802(10) (emphasis added). Authorization to dispense does not include authorization to distribute and vice versa. See 21 U.S.C. 802(11) (specifically excluding “dispense” from the definition of “distribute”). As such, registration to dispense specifically conveys narrow authority to deliver a controlled substance *to an ultimate user pursuant to the lawful order of a practitioner*. Registrants who are only authorized to dispense controlled substances (e.g., practitioners) are therefore not authorized to deliver these substances themselves to any entity other than an ultimate user, even for the purpose of disposal. Instead, practitioners may only deliver

⁴⁰ Defined by the CSA as “a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.” 21 U.S.C. 802(21). Under the CSA, “[t]he Attorney General shall register practitioners . . . to dispense, or conduct research with, controlled substances . . .” 21 U.S.C. 823(f).

these substances to authorized persons by common or contract carrier or by pick-up at the practitioner's registered location.

As discussed, non-practitioners (e.g., manufacturers, distributors, and reverse distributors) are not similarly limited in their authority to lawfully deliver controlled substances. DEA therefore proposes in section 1317.05(b) to allow non-practitioners to deliver (i.e., transfer) controlled substances themselves for the purpose of disposal provided that such substances are transported directly to the destruction location and accompanied by two authorized employees. This proposed requirement is consistent with existing practices by registered manufacturers, distributors, and reverse distributors when transporting and disposing of controlled substances. These non-practitioners generally follow these procedures (in addition to various other procedures) as a counter-measure against theft and diversion. DEA proposes these procedures, along with the procedures set forth at section 1317.95, as the minimum required to help ensure the physical security of highly pilferable controlled substances and as a deterrent to theft and diversion.

Consistent with the requirements of the Controlled Substances Act, DEA proposes in section 1317.05(b) to authorize non-practitioners to dispose of their controlled substance inventory in one of four ways: (1) promptly destroy the substance using an on-site method of destruction in accordance with applicable federal, state, tribal, and local laws and regulations (as required by section 1317.90); (2) promptly deliver the substance to a registered reverse distributor at its registered location by common or contract carrier, or by reverse distributor pick-up; (3) for the purpose of return or recall, promptly deliver the substance by common or contract carrier or pick-up at the registrant's registered location to the person from whom it was obtained, the registered

manufacturer of the substance, or another registrant authorized by the manufacturer to accept returns or recalls; or (4) promptly transport the substance by its own means to the registered location of a reverse distributor, the location of destruction, or the registered location of any person authorized to receive the substance for the purpose of return or recall.

As discussed, a practitioner's registration does not convey authority to distribute, deliver, or otherwise transfer controlled substances to any entity other than an ultimate user. Accordingly, DEA proposes in section 1317.05(a) to authorize practitioner registrants to dispose of their controlled substance inventory in one of four ways: (1) promptly destroy the substance using an on-site method of destruction in accordance with applicable federal, state, tribal, and local laws and regulations (as required by section 1317.90); (2) promptly deliver the substance to a reverse distributor at its registered location by common or contract carrier, or by reverse distributor pick-up;⁴¹; (3) for the purpose of return or recall, promptly deliver the substance to the registered person from whom the substance was obtained, the registered manufacturer of the substance, or another registrant authorized to accept returns or recalls by common or contract carrier or by pick-up at the registrant's registered location; or (4) request assistance from the Special Agent in Charge of the Administration in the area in which the practitioner is located. DEA proposes to allow practitioner registrants to retain the existing ability to request assistance from the SAC in the area in which the practitioner is located to dispose of their controlled substances, similar to the existing provisions of section 1307.21, in

⁴¹ Current DEA regulations at 21 CFR 1307.11(a)(2) discuss practitioner distribution of controlled substances to a reverse distributor. DEA proposes to clarify that provision at the proposed section 1317.05. As such, DEA proposes to delete 21 CFR 1307.11(a)(2) to eliminate redundancy.

order to expand the options available for practitioners to destroy controlled substances or cause controlled substances to be destroyed. DEA proposes that the SAC in the practitioner's area may authorize the practitioner to: transfer the controlled substances to a person registered under the Act and authorized to transport and destroy the substance; deliver the substances to an agent of the DEA or the nearest DEA office; or destroy the substances in the presence of an agent of the DEA or other authorized person. In circumstances in which a practitioner regularly destroys controlled substances, the practitioner may do so on a regular basis upon instructions from the relevant SAC.

Registrants that destroy controlled substances must do so promptly, unless otherwise specified. DEA is proposing the flexible "prompt" destruction standard rather than a specific time frame for destruction to ensure that controlled substances do not accumulate while pending destruction and are destroyed in a timely manner, while still accounting for the individual circumstances of registrants that destroy controlled substances.

For all registrants that destroy controlled substances or cause controlled substances to be destroyed (e.g., by transferring the substance to an authorized reverse distributor or transporting the substance to an off-site, unregistered location for destruction), DEA proposes in section 1317.95 that such registrants be required to follow certain security procedures related to employees, transportation, loading and unloading, handling, and destruction. DEA is proposing enhanced security requirements in order to strengthen the integrity of the disposal process, which has been expanded to include more disposal options and eliminates the requirement of prior notice of destruction to DEA, by filing DEA Form 41 prior to destruction, in every instance except when

practitioners seek disposal assistance pursuant to proposed section 1317.05(a)(4). When a DEA registrant that destroys or causes the destruction of controlled substances is the last registered person to possess such substances, the registrant must follow increased security measures at the point of destruction to ensure accountability and effectively minimize the risk of diversion.

For registrants that destroy controlled substances on-site, that maintain possession of controlled substances until they are rendered non-retrievable (e.g., when transporting substances to an unregistered location for destruction), or that transfer custody to an authorized person for disposal, DEA is proposing employee security requirements in section 1317.95 to ensure that only employees that have satisfied certain employee screening requirements are authorized to oversee the handling of controlled substances during the destruction process. Under the proposed definition in 1317.02(a), an “authorized employee” is a person directly employed by the registrant full time (i.e., not employed as a contractor or agent of a third party) who must not have been convicted of any felony offense related to controlled substances and not have had at any time an application for registration with DEA denied, had a DEA registration revoked or suspended, or surrendered a DEA registration for cause.

The proposed security measures include the requirement that two authorized employees load and unload (or observe the loading and unloading of) controlled substances during transfer of the substances to another registrant; and, if the substances are destroyed on a registrant’s registered premises, two authorized employees shall personally witness the destruction and shall handle (or observe the handling of) the substance until it is rendered non-retrievable. This two-person integrity requirement is

necessary because the destroying registrant is the last person authorized to handle the substance before destruction and this requirement will reduce the opportunity for diversion and help to ensure that the controlled substances are actually destroyed and not diverted to illicit use.

Additionally, DEA proposes in section 1317.100 that a registrant that destroys controlled substances or causes the destruction of controlled substances is required to maintain a record of the destruction in a form to be issued by DEA. This form will be DEA Form 41. At present, DEA Form 41 is used as a record of destruction by registrants. DEA is proposing to modify DEA Form 41 to act as the record of destruction, including the signature of the two authorized employees witnessing the destruction. In an effort to minimize the burden on registrants, and in accordance with the proposed comprehensive new part on disposal, registrants that destroy or cause the destruction of controlled substances and utilize DEA Form 41 will no longer be required to submit three copies of DEA Form 41 to the SAC in their area, except one copy shall be submitted by practitioners seeking assistance pursuant to section 1317.05(a). Rather, in accordance with the CSA, such registrants will be required to keep and make available that record, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General. 21 U.S.C. 827. Furthermore, all methods of destruction must be conducted in accordance with all applicable federal, state, local, and tribal laws and regulations.

Reverse Distributors

Reverse distributors are a unique group of registrants whose primary function is to possess controlled substances for the purpose of destruction or return. In this regard,

reverse distributors provide a valuable service to other registrants in the disposal process. In the distribution of controlled substances between registrants, each registrant serves as a check on the other and verifies whether the controlled substance has reached its lawful destination. This is accomplished through existing reporting, recordkeeping, and order form requirements. 21 U.S.C. 827 – 828; 21 CFR part 1304 and 21 CFR part 1305. However, a reverse distributor that acquires controlled substances from another registrant for destruction is the last person to possess such substance before destruction so there is no recipient to verify that the substance has been destroyed. Furthermore, reverse distributors accumulate greater amounts of controlled substances that are destined for destruction in comparison to other registrants. This is because reverse distributors routinely acquire controlled substances for destruction from other registrants and may also be authorized as collectors. As a result, DEA is proposing security and recordkeeping requirements that apply specifically to a reverse distributor's unique function.

The existing regulations pertaining to reverse distributors are located in different parts of the CFR. DEA is proposing revised regulations for reverse distributors that are clear, consistent, and consolidated into one part.⁴² DEA believes that these proposed regulations will help reverse distributors comply with the Controlled Substances Act in a manner that effectively decreases the risk of diversion of controlled substances during the disposal process.

DEA proposes to revise the definition of reverse distributor in section 1300.01(b).

⁴² While reverse distributor-specific regulations are consolidated into proposed new 21 CFR part 1317, registered reverse distributors will still be required to follow all other applicable regulations that fall outside 21 CFR part 1317.

In the existing regulations, a reverse distributor is permitted to acquire controlled substances from other registrants for the purpose of return to the manufacturer or manufacturer's agent, or "to process for or arrange the processing for" disposal. DEA proposes to revise the definition of "reverse distributor" by first defining "reverse distribute" to mean "to acquire controlled substances from another DEA registrant or a law enforcement agency for the purpose of: (1) return to the manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf, or (2) destruction." A "reverse distributor" is a person who reverse distributes a controlled substance.

In the existing definition of reverse distributor, a reverse distributor is permitted to acquire controlled substances from other registrants for the purpose of return to the manufacturer or manufacturer's agent. DEA proposes revising the definition to authorize a reverse distributor to acquire controlled substances from another DEA registrant for the purpose of return to the manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf. This revision is proposed so that the reverse distribute definition is consistent with the proposed revisions to return and recall in sections 1317.05 and 1317.85 (discussed below). DEA believes that this new definition clearly and accurately reflects the proper role of a reverse distributor.

DEA proposes in section 1317.15(b) to authorize registered reverse distributors to acquire controlled substances from other registrants in one of two ways: (1) pick-up the controlled substance from a registrant at the registrant's registered location ("pick-up"), or (2) receive the controlled substance from a registrant at the reverse distributor's registered location, delivered directly by a non-practitioner or by common or contract

carrier (“delivery”). Once en route from a registrant’s registered location to a reverse distributor’s registered location, shipments or packages of controlled substances may not be re-routed to another person or location, even if that person or location is registered with DEA. DEA believes that re-routing shipments or packages destined for one registrant to another registrant substantially increases the likelihood of diversion.

DEA proposes in section 1317.15(c) that upon acquisition of a controlled substance from a registrant, a reverse distributor must either: (1) immediately store the controlled substance at, or transfer the controlled substance to, the reverse distributor’s registered location for secure storage until timely destruction or timely return to the registered manufacturer of the substance can occur, (2) immediately deliver the controlled substance to the manufacturer or manufacturer’s agent, (3) timely destroy the controlled substance, or (4) immediately deliver the controlled substance to the place of destruction for timely destruction. The requirement for “immediate” transfer or delivery is intended to ensure that shipments or packages are continuously moving towards their ultimate, secure destination. Such continuous movement reduces the risk of diversion by limiting the opportunity for theft or loss. Consistent with 21 CFR 1301.12(b)(4) and the existing definition of “freight forwarding facility” in 21 CFR 1300.01(b), a reverse distributor may not operate freight forwarding facilities for purposes of transporting controlled substances. DEA proposes to clarify this by specifically excluding reverse distributors from the definition of “freight forwarding facility” in section 1300.01(b).

DEA is also proposing in section 1317.15(d) to require reverse distributors to destroy or cause the destruction of any controlled substances received for the purpose of destruction as soon as practicable but no later than within fourteen calendar days of pick-

up or delivery. A reverse distributor that acquires a controlled substance for destruction is the last person to possess such substance before destruction and, therefore, must follow increased security measures. The “as soon as practicable but no later than fourteen calendar day” requirement is unique to reverse distributors – other registrants that destroy must do so promptly and do not have to follow a specific time limit – because the primary business activity of reverse distributors, unlike other registrants, is to acquire controlled substances for the purpose of destruction or return. As a result, reverse distributors generally accumulate greater amounts of controlled substances that are destined for destruction in comparison to other registrants. They are typically the last registrant to handle the controlled substance with no other registrant reporting and recording receipt of the substance as a check against diversion. The “as soon as practicable but no later than fourteen calendar day” requirement will ensure that reverse distributors destroy or cause the destruction of controlled substances in a timely manner while also enabling them sufficient time to prepare the necessary records required for destruction. In addition, the “as soon as practicable but no later than fourteen calendar day” requirement will reduce the risk of diversion by limiting the opportunity for theft or loss. This is necessary because, just as there is a greater risk of diversion when controlled substances are being transported for the purposes of destruction, there is a greater risk of diversion the longer a substance destined for destruction remains in storage awaiting destruction.

DEA is proposing to specify a maximum time limit for reverse distributors to destroy or cause the destruction of any controlled substance received for the purpose of destruction—as soon as practicable but no later than fourteen calendar days of receipt

(pick-up or delivery). While DEA believes that the majority of reverse distributors already destroy or cause the destruction of controlled substances received for the purpose of destruction as soon as practicable but no later than fourteen calendar days of receipt, DEA recognizes that some may not. For the reverse distributors that do not currently meet this standard, this requirement may cause these reverse distributors to incur additional costs through more frequent transportation of controlled substances to the point of destruction and destruction of partial loads. For purposes of this proposal, DEA assumes that some reverse distributors may have to adjust current business operations in order to comply with this new requirement, such as by restricting the receipt of deliveries to their registered location to specific days and/or amounts, or by changing pick-up routes to accommodate the requirement that any controlled substance received for the purpose of destruction be destroyed as soon as practicable but no later than fourteen calendar days of receipt.

DEA believes that the proposed “as soon as practicable but no later than fourteen calendar day” requirement is reasonable and will reduce the risks of diversion. However, DEA also acknowledges that there are assorted federal, state, and local transportation and environmental laws and regulations that reverse distributors must comply with in addition to those under the CSA and these proposed regulations. DEA also acknowledges that these proposed regulations may result in reverse distributors choosing to be responsible for much more controlled substances than they are currently responsible. Accordingly, DEA invites comments on the practicability of implementing the “as soon as practicable but no later than fourteen calendar day” requirement while also maintaining effective controls against diversion. Considering there are currently a limited number of registered

reverse distributors with significant variations in current business practices across the United States, DEA seeks information regarding how the “as soon as practicable but no later than fourteen calendar day” destruction requirement would impact business practices, if at all, with specific focus on the potential long-term and short-term costs of implementing this requirement, and whether such costs would be offset by other measures. DEA also invites comment regarding the effects that shorter and longer time limits for destruction—specifically, as soon as practicable but no later than seven calendar days or thirty calendar days for destruction – would have on current business practices, including the physical security controls and operating procedures that would be implemented or modified in order to guard against theft and diversion, and the potential costs that may be incurred as a result of alternative time limits.

DEA is also proposing in section 1317.20 enhanced employee security requirements for reverse distributors. DEA proposes that reverse distributors be prohibited from employing, as an agent or employee who has access to or influence over controlled substances, any person that has ever been convicted of any felony offense related to controlled substances or has ever had an application for registration with DEA denied, had a DEA registration revoked or suspended, or surrendered a DEA registration for cause. DEA is proposing these enhanced security requirements for reverse distributors in order to strengthen the integrity of the disposal process by ensuring that only certain employees are authorized to have access to or influence over controlled substances. This requirement is similar to existing employee security requirements for registered practitioners in 21 CFR 1301.76(a), where there is a high risk of diversion and limited physical security requirements.

DEA is also proposing in 1317.25 to streamline and clarify recordkeeping requirements for registered reverse distributors that acquire controlled substances from other registrants so that they are consistent and accurately reflect reverse distributor authorized activities in compliance with the Controlled Substances Act. These requirements are separate from the recordkeeping requirements for reverse distributors that acquire controlled substances from law enforcement agencies and authorized collectors, as discussed above, in proposed section 1317.55.

First, the existing regulations require registered reverse distributors to record in an inventory, information regarding specific quantities of controlled substances that is different from the information required in continuing records. 21 CFR 1304.11(e)(3) and 1304.22(e). To reconcile this discrepancy, DEA proposes in sections 1317.25(b) and (c) that in both inventory and continuing records, a reverse distributor must record the quantity of a controlled substance in both finished and bulk form, and the quantity contained in a commercial container, carton, crate, drum, or other receptacle that has been opened.

Second, in accordance with the CSA, every DEA registrant must maintain, on a current basis, a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of. 21 U.S.C. 827(a). These records must be maintained separately from all other records of the registrant or, alternatively, in the case of non-narcotic controlled substances, be in such a form that required information is readily retrievable from the ordinary business records of the registrant. 21 U.S.C. 827(b)(2). The records must be kept and be available for at least two years for inspection and copying by officers or employees of the Attorney General. 21 U.S.C.

827(b)(3). Under its statutory authority, DEA may promulgate regulations that specify the information that registrants are required to maintain in their records. 21 U.S.C.

827(b).

To this end, DEA proposes in section 1317.25(c) to require registered reverse distributors to: (1) keep records regarding each controlled substance received from another registrant for the purpose of return to a manufacturer or, if designated, to another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf, and (2) keep records regarding each controlled substance destroyed, including information pertaining to the receipt and destruction of the controlled substance. These records, similar to the current requirements in 21 CFR 1304.22(e) that DEA proposes to delete, are necessary for inspection to maintain the integrity of the closed system and to assist in the detection and prevention of diversion.

DEA proposes in section 1317.25(c)(4) that for all controlled substance records, reverse distributors will be required to maintain the record of receipt with the corresponding record of return or destruction. By maintaining all relevant records together, DEA will be able to account for each substance received by a reverse distributor from its acquisition to its disposition, whether by destruction or return to the manufacturer. DEA also emphasizes that each registrant must prepare and maintain separate and independent records in order to ensure accountability of each registrant, and the integrity of the closed system of distribution.

Return and Recall

DEA is proposing to delete the existing rule on return and recall, 21 CFR 1307.12, and to clarify and separate the role of registrants and non-registrants in the

return and recall of controlled substances. This is because of the different circumstances surrounding registrant and ultimate user return and recall.

Return and Recall by Registrants

DEA proposes procedures for the return and recall of controlled substances by DEA registrants in sections 1317.05(a)(3), 1317.05(b)(3), and 1317.05(b)(4), and recordkeeping and order form requirements in a new section 1317.10, which are similar to the existing rule on return and recall in 21 CFR 1307.12. The proposed new sections, however, clarify which registrants are authorized to distribute and receive returns and recalls and clarifies the recordkeeping and order form requirements. DEA proposes in sections 1317.05(a)(3), 1317.05(b)(3), and 1317.05(b)(4) that registrants in lawful possession of a controlled substance may return that substance for the purpose of return or recall to: (1) the registered person from whom it was obtained; (2) the registered manufacturer of the substance; or (3) another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf. The procedures governing return of the substance are determined by the returning registrant's authorization as a practitioner or non-practitioner, as discussed above. This is consistent with the intent of the Controlled Substances Act to prevent opportunities for diversion because the substances are being transferred within the closed system of distribution for the purpose of disposal (i.e., return or recall) without having left the closed system of distribution, and accountability is ensured by pertinent recordkeeping requirements.

DEA proposes in section 1317.10(a) information that must be maintained in the records of registrants returning controlled substances and registrants receiving returns. In addition, pursuant to proposed section 1317.10(b), DEA Form 222 must be used by each

registrant that distributes a controlled substance in Schedule I or II for the purpose of return and recall in accordance with 21 CFR part 1305. The freight forwarding provision of the existing rule is also retained in section 1317.10(c).

Ultimate User Product Recall

DEA proposes in section 1317.85 procedures for the recall or return of controlled substances by ultimate users. Currently, DEA authorizes ultimate user distribution for the purpose of recall under existing 21 CFR 1307.12, but the language in this section is overly broad. The proposed section 1317.85(a) reduces ambiguity that exists under current regulations by specifying to whom an ultimate user is permitted to deliver their recalled controlled substance and by outlining consistent and clear requirements for registrants authorized to receive those recalled substances from ultimate users.

In particular, DEA proposes in section 1317.85(a) to authorize an ultimate user in lawful possession of a controlled substance in Schedules II, III, IV, or V to deliver the recalled controlled substance to the manufacturer of the substance or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf. In the event of a product recall, the manufacturer of the recalled controlled substance or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf is authorized to receive recalled controlled substances from an ultimate user and does not need to be an authorized collector to do so. This is because the necessary security and experience in handling controlled substances is already in place. Recalled controlled substances received by authorized registrants from ultimate users are re-entering the closed system of distribution and must be handled (stored, destroyed, etc.), unless otherwise specified, in accordance with procedures that the

registrant is otherwise required to follow.

DEA proposes in 1317.85(a)(1) that registrants authorized to receive recalled controlled substances from ultimate users maintain a record of recalled controlled substances received from ultimate users. Those registrants, however, are exempted under section 1317.85(a)(2) from the requirements in 21 CFR part 1305 pertaining to DEA Form 222 for substances received from non-registrants. In accordance with the Disposal Act, the delivery of a Schedule II controlled substance for the purpose of disposal by an ultimate user, long-term care facility, or other person acting in accordance with the Disposal Act is exempt from order form requirements (i.e., an ultimate user or long-term care facility may transfer a Schedule II controlled substance to another person for the purpose of disposal without a written order of the person to whom such substance is transferred). 21 U.S.C. 828(b)(3). In other words, when an ultimate user delivers a recalled controlled substance to an authorized registrant for the purpose of disposal, in this case recall, such transactions are exempt from the requirements found in 21 CFR part 1305.

DEA is also proposing in section 1317.85(a)(3) that the authorized registrant report all recalled controlled substance acquisition transactions pursuant to 21 CFR 1304.33. Such registrants may report either each individual receipt or a single transaction that includes all recalled controlled substances of the same name and finished form (e.g., all 10-milligram tablets or all 5-milligram concentration per fluid ounce or milliliter) received from ultimate users.

Finally, DEA proposes in 1317.85(b) that an ultimate user that is participating in an investigational use of drugs pursuant to 21 U.S.C. 355(i) and 360b(j) and wishes to

deliver any unused controlled substance received as part of that research to the registered dispenser from which it was obtained, may do so in accordance with regulations promulgated by the Secretary of Health and Human Services pursuant to 21 U.S.C. 355(i) and 360b(j).

Methods of Destruction

DEA is proposing a standard of destruction – non-retrievable – for persons that destroy or cause the destruction of controlled substances. Some examples of current technology that may achieve the non-retrievable standard are incineration and chemical digestion. Flushing and mixing controlled substances with coffee grounds or kitty litter are examples of existing methods of destruction that do **not** meet the non-retrievable standard. These examples are not exhaustive and DEA is not requiring, endorsing, authorizing, or recommending any particular method of destruction so long as the desired result is achieved and the method is compliant with all applicable federal, state, tribal, and local laws and regulations. This standard is intended to allow public and private entities to develop a variety of destruction methods that are secure, convenient, and responsible, consistent with preventing the diversion of such substances. DEA is proposing a standard of destruction that provides communities the flexibility to tailor disposal options to meet their resources and needs and allows for advances in technology.

Non-retrievable

Each controlled substance has its own inherent chemical and/or physical properties. Accordingly, the objective of “destruction” is to render the substance no longer susceptible to diversion for an illicit or non-medical use. DEA intends to provide maximum flexibility to allow for technological innovation and development in controlled

substance destruction processes. As such, DEA solicits comments on the proposed requirement that all destruction processes be applied in such a manner that the controlled substances are rendered “non-retrievable.”

Any destruction method applied to a controlled substance must render it “non-retrievable.” The proposed definition of “non-retrievable” means to permanently alter any controlled substance’s physical and/or chemical state through irreversible means in order to render that controlled substance unavailable and unusable for all practical purposes. This definition is not intended to require destruction beyond the state at which a controlled substance becomes unavailable, unusable and, subsequently, no longer available for diversion.

In the case of ultimate user disposal where most people are unable to differentiate between controlled and non-controlled substances and because cataloging or taking inventory of substances may be detrimental to efforts to prevent diversion, all of the proposed collection methods allow comingling of pharmaceuticals. As a result, this proposed rule would require a method of destruction sufficient to render all included controlled substances non-retrievable. Likewise, where the actual substances collected are unknown, but may reasonably include controlled substances, the proposed rule would require selection of a method of destruction sufficient to render non-retrievable any controlled substance likely to be present. Information received at the January 2011 public meeting held by DEA indicated that incineration in accordance with federal, state, and local law may be the currently most-used method of destruction to achieve this result. Even so, DEA is proposing a standard that allows flexibility so long as the desired result is achieved, thus allowing for technological innovation and development. Regardless of

the destruction method, the destruction must be conducted in accordance with all federal, state, tribal, and local laws and regulations.

Environmental Considerations

In passing the Disposal Act to provide those individuals seeking to dispose of unwanted or unused controlled substances in their household with more disposal options beyond discarding or flushing the substances, Congress expected that there would be fewer such substances introduced into the environment, particularly into the water.⁴³

DEA also recognizes that the establishment of alternative, lawful means for disposing of unused or expired pharmaceutical controlled substances may alleviate some existing environmental concerns. For example, recent studies have reported on the presence of pharmaceutical chemicals in varying concentrations in water supplies. DEA is hopeful that the increased availability of methods for citizens to safely and securely dispose of unwanted prescription drugs will have a positive impact on reducing the introduction of chemical contaminants into the water supply. However, collection and destruction of unwanted and unused pharmaceuticals cannot and will not address water contamination that occurs from other means such as bodily elimination or excretion of such substances.

The requirements of this proposed rule only govern compliance with the Controlled Substances Act. Any selected method of destruction of controlled substances meeting the requirements of this proposed rule must also comply with all applicable federal, state, and local laws and regulations applicable at the time of the destruction. Because of the broad range of such environmental and other laws and regulations, this

⁴³ See Findings, Sec. 2, Secure and Responsible Drug Disposal Act of 2010.

proposed rule does not purport to address what laws may or may not be applicable in a particular circumstance now or at some future date.

As DEA and public and private entities introduce proposed options for disposal of controlled substances to the general public and in specific communities, it is anticipated that the environmental benefits of proper collection and destruction will be emphasized in the public education and publicity surrounding the disposal of unwanted or unused controlled substances. Public health and safety is protected and improved both in preventing diversion of controlled substances during a national epidemic of pharmaceutical drug abuse and in providing options for collection that result in secure and environmentally sound destruction consistent with federal, state, tribal, and local laws and regulations.

Miscellaneous Changes

In accordance with the changes described above, DEA proposes to delete any reference to 21 CFR 1307.12 and 1307.21 and replace it with a reference to the new 21 CFR part 1317, where appropriate.⁴⁴ DEA also proposes to revise 21 CFR 1301.13(e)(1)(i) to delete reference to a disposer category of registration in the coincident activity column for manufacturers. A disposer category of registration was proposed by DEA in 1995, but was never finalized (60 FR 43732, August 23, 1995). Reference to a disposer category was inadvertently included in a previous rulemaking (68 FR 58587,

⁴⁴ DEA proposes in 21 CFR 1301.76 to delete reference to 1307.12 and replace it with reference to 21 CFR part 1317; in 21 CFR 1304.11(e) and the introductory paragraph of 1304.22 to delete reference to 21 CFR 1307.12; in 21 CFR 1301.25(i), 1301.52(c), and 1307.13 to delete reference to 21 CFR 1307.21 and replace it with reference to 21 CFR part 1317; in 21 CFR 1304.25(a)(9) and 1304.25(b)(9) to delete reference to 21 CFR 1307.22 and replace it with reference to 21 CFR part 1317; and in 21 CFR 1304.04(a) to add reference to 21 CFR part 1317. DEA also proposes in 21 CFR 1307.22 to delete reference to 21 CFR 1307.21, but not replace it with reference to 21 CFR part 1317. This revision to 21 CFR 1307.22 will allow existing practices for seizure and forfeiture to continue. DEA proposes to revise the title of 21 CFR 1307.22 to “Delivery of forfeited controlled substances” for clarity.

October 10, 2003).

Regulatory Analyses

Regulatory Flexibility Act

Under the Regulatory Flexibility Act of 1980 (RFA) (5 U.S.C. 601-612), federal agencies must evaluate the impact of rules on small entities and consider less burdensome alternatives. As discussed in the preceding sections of the regulatory preamble, DEA has considered numerous alternatives for each proposed requirement and method of collection and evaluated the impact of this proposed rule on small entities. DEA has concluded that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. An economic analysis of the Proposed Rule can be found in the rulemaking docket at <http://www.regulations.gov>.

In developing this proposed rule, DEA considered several options for both registrant and non-registrant disposal and reverse distributor destruction requirements. DEA analyzed alternative methodology approaches keeping in mind its statutory obligations under the CSA. DEA considered three options for non-registrant disposal: (1) Single Collection, which would authorize non-registrants to utilize only one method of collection to dispose of their lawfully possessed controlled substances; (2) Open Collection, which would authorize any person to collect controlled substances from ultimate users for disposal, regardless of their status as a DEA registrant; and (3) Multiple Collection, which would authorize non-registrants to utilize more than one method of collection to transfer controlled substances for purposes of disposal to law enforcement agencies and certain DEA registrants. In addition, DEA considered two options for registrant disposal: (1) Retain Existing Regulations, which would make no changes to

the existing registrant disposal regulations (21 CFR 1307.12 and 1307.21); and (2) Establish Consistent National Standards, which would delete existing regulations on the disposal of controlled substances (21 CFR 1307.12 and 1307.21) and promulgate a new part that would comprehensively outline the process and procedure for the disposal of controlled substances by registrants and non-registrants.

Finally, DEA considered four options for reverse distributors: (1) On-site Requirement, which would require reverse distributors to have and utilize an on-site method of destruction; (2) Prompt Requirement, which would require reverse distributors, like all other registrants, to promptly destroy controlled substances; (3) No Requirement, which would retain the current destruction standard and would not put a timeline on when reverse distributors must destroy controlled substances acquired for destruction; and (4) As Soon As Practicable But No Later Than Fourteen Calendar Day Requirement, which would require reverse distributors to destroy controlled substances received for the purpose of destruction as soon as practicable but no later than fourteen calendar days of receipt. DEA performed a qualitative analysis of each of these alternatives and selected the “Multiple Collection” option for non-registrant disposal, the “Establish Consistent National Standard” option for registrant disposal, and the “As Soon As Practicable But No Later Than Fourteen Calendar Day Requirement” option for reverse distributors.

In accordance with the RFA, DEA evaluated the impact of this rule on small entities and anticipates that this rule will not have a significant economic impact on a substantial number of small entities. If promulgated, this proposed rule would affect all 1.4 million controlled substance registrants, which corresponds to approximately 381,386

businesses affected by the proposed rule. DEA estimates that 370,133 (97 percent) of the affected businesses are considered “small entities” in accordance with the RFA and Small Business Administration (SBA) standards. 5 U.S.C. 601(6) and 15 U.S.C. 632. DEA estimates that there should be minimal to no economic impact as a result of this proposed rule.

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Administrator hereby certifies that this proposed rulemaking has been drafted consistent with the Act and that a regulatory analysis on the effects or impacts of this proposed rulemaking on small entities has been done and that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Executive Orders 12866 and 13563

This proposed rule was developed in accordance with the principles of Executive Orders 12866 and 13563. Based on an economic analysis, DEA does not anticipate that this rulemaking will have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities. An economic analysis of the Proposed Rule can be found in the rulemaking docket at <http://www.regulations.gov>. Public comment was received in public meetings held on January 19-20, 2011, to help inform and develop these proposed rules. Public comment is encouraged on this proposed rule through the internet with easy access to supporting information found at <http://www.regulations.gov>. Although not an economically significant rule, this proposed rule on the disposal of controlled substances has been reviewed by the Office of Management and Budget.

For DEA registrants that destroy controlled substances as described above, DEA anticipates that this rulemaking will have minimal or no economic impact and that modified DEA Form 41 could result in some level of cost savings. In addition, for registered reverse distributors, DEA anticipates that the security and recordkeeping requirements contained in the proposed rule will result in minimal or no costs.

DEA has determined that reverse distributors currently destroy controlled substances within the proposed “as soon as practicable but no later than fourteen calendar day” requirement the majority of the time. However, it is recognized that there may be instances when reverse distributors do not currently meet this proposed requirement. For these instances, DEA believes reverse distributors will be able to make modifications to their pick-up/receipt and destruction schedule to accommodate the proposed requirements with minimal to no economic impact. Moreover, DEA conservatively estimates that the voluntary provisions for collectors, reverse distributors, distributors, and law enforcement agencies will have a net economic impact of nearly zero, and invites comment on this estimate. The proposed provisions that facilitate Non-Registrant Disposal are completely voluntary, not mandated. Any collector, reverse distributor, distributor, or law enforcement agency may choose to engage in the voluntary activities based on its own evaluation of costs and benefits (tangible and intangible). For the purposes of this analysis, DEA assumes that an entity will volunteer to perform the activities to facilitate Non-Registrant Disposal only if there is a net zero or positive benefit to the entity. For example, a pharmacy may derive tangible benefits, such as additional revenue from increased retail traffic to the pharmacy. Collectors may also derive tangible benefits such as public safety and good will from its collection activities. Any collector, reverse

distributor, distributor, or law enforcement agency that chooses to engage in these voluntary activities can decide to cease these activities at any time. Therefore, for the purposes of this analysis, DEA estimates that the voluntary provisions in this section have net zero economic impact on the regulated entities.

In summary, DEA estimates that there should be minimal to no annual total cost to the economy as a result of the proposed rule. Accordingly, DEA does not anticipate that this rulemaking will have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities.

In evaluating the costs and benefits of the rule, the annual cost of the rule is compared with the anticipated reduction in the growth rate of costs associated with diversion of controlled substances and listed chemicals into the illicit market. The cost-benefit analysis uses the costs associated with the nonmedical use of prescription opioids, \$8.6 billion in 2001⁴⁵ and \$53.4 billion in 2006.⁴⁶ These are conservative estimates of the rapidly growing total cost associated with diversion of controlled substances and listed chemicals into the illicit market. As DEA has determined this rule poses minimal to no economic impact, DEA concludes that this rule reduces the growth in the cost of the diversion of controlled substances and listed chemicals into the illicit market, therefore, this rule will have a positive benefit for the health and safety of the citizens and residents of the United States.

⁴⁵ Clin J Pain (The Clinical Journal of Pain), Volume 22, Number 8, October 2006.

⁴⁶ Clin J Pain (The Clinical Journal of Pain), Volume 27, Number 3, March/April 2011.

Paperwork Reduction Act

Pursuant to Section 3507(d) of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 et seq.), DEA has identified the following collections of information related to this proposed rule on the disposal of controlled substances and has submitted these collection requests to the Office of Management and Budget (OMB) for review and approval. This proposed rule implements the Secure and Responsible Drug Disposal Act of 2010 (Disposal Act), in addition to reorganizing and consolidating existing regulations on disposal into a comprehensive regulatory framework for the destruction of controlled substances. In accordance with the Controlled Substances Act (CSA), which establishes a closed system of distribution for all controlled substances, DEA registrants are required to make a biennial inventory and maintain, on a current basis, a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of. 21 U.S.C. 827(a). These records must be in accordance with and contain such relevant information as may be required by regulations promulgated by DEA. 21 U.S.C. 827(b)(1). In this rule, DEA proposes to revise existing and add a minimum amount of new registrant recordkeeping requirements, which are consistent with those requirements that are already required by statute and the proposed new part on disposal that creates a comprehensive regulatory framework for the destruction of controlled substances.

Title: Implementation of Registrant Recordkeeping Requirements Pursuant to the Controlled Substances Act, 21 U.S.C. 827

The recordkeeping requirements that DEA registrants are required to maintain pursuant to law are a vital component of DEA's enforcement and control responsibilities

– such records alert DEA to problems of diversion and ensure that the system of controlled substances distribution is open only to legitimate handlers of such substances.

As discussed in the section on reverse distributors above, DEA is proposing to revise the information that registered reverse distributors are currently required to record consistent with previous requirements as well as a minimum amount of requirements under the proposed new comprehensive regulatory framework for the destruction of controlled substances. As discussed in more detail above, DEA proposes to modify the existing information that reverse distributors are required to record for clarity and consistency. In addition, DEA proposes that for all controlled substance records, reverse distributors will be required to maintain their existing business records so that the record of receipt is maintained with the corresponding record of return or destruction. By maintaining all relevant business records together, DEA will be able to trace each substance received by a reverse distributor from its acquisition to its disposition, whether by destruction or return to the manufacturer.

DEA estimates that there will be 60 respondents to this information collection and that their estimated frequency of response will vary. DEA estimates that the frequency of response will vary, because in accordance with 21 U.S.C. 827(a), registrants make an initial and biennial inventory and maintain, on a current basis, a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of. Because DEA is proposing recordkeeping requirements that registered reverse distributors are already required to maintain in accordance with 21 U.S.C. 827(a) and (b), DEA anticipates that the annual hour burden will not be increased by the proposed rule.

DEA is also proposing revised information that registrants are required to record in the return and recall process. DEA proposes to delete the existing rule on return and recall, 21 CFR 1307.12, and to implement separate rules on the return and recall of controlled substances for registrants and non-registrants. The return and recall recordkeeping requirements have been revised to reflect these changes.

DEA estimates that the universe of potential respondents to this information collection will be 68,344 respondents (Distributors - 828, Reverse Distributors - 60, Manufacturers - 522, Retail Pharmacies - 66,934). DEA estimates that the frequency of response will vary, because in accordance with 21 U.S.C. 827(a), registrants make an initial and biennial inventory and maintain, on a current basis, a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of. Because DEA is proposing recordkeeping requirements that registrants are already required to maintain in accordance with 21 U.S.C. 827(a) and (b), DEA anticipates that the annual hour burden will not be increased by the proposed rule.

DEA is proposing new recordkeeping requirements for registrants that collect controlled substances from ultimate users and other non-registrants in accordance with the new authority provided in the Disposal Act. To implement the Disposal Act, DEA is proposing to provide ultimate users, long term care facilities, and other non-registrants safe and convenient options to transfer controlled substances for purposes of disposal: take-back events, mail-back programs, and collection receptacle locations. In the proposed rule, registered manufacturers, distributors, reverse distributors, and retail pharmacies may obtain authorization from DEA to be a collector. A collector is a registered person authorized to receive a controlled substance for the purpose of disposal

from non-registrants in lawful possession of controlled substances. DEA is proposing information that collectors must record based on the particular ultimate user collection method utilized (i.e., mail-back program or collection receptacle).

DEA estimates that the universe of potential participants to this information collection will be 68,344 respondents (Distributors - 828, Reverse Distributors - 60, Manufacturers - 522, Retail Pharmacies - 66,934).⁴⁷ DEA estimates that the frequency of response will vary, because in accordance with 21 U.S.C. 827(a), registrants make an initial and biennial inventory and maintain, on a current basis, a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of. DEA notes, however, that the option to become an authorized collector is voluntary and no entity is required to establish or operate a disposal program as an authorized collector. The authorization to collect is a new activity and DEA has no criterion to determine the level of participation. As a result, the number of respondents is based on the current number of registrants which may request authorization to become a collector and the annual hour burden cannot be determined at this time. DEA will continue to monitor and analyze the potential burden of the new requirements imposed by this proposed rule and will review all comments submitted in response to this proposed rule and information collection request.

DEA is also proposing to authorize registered reverse distributors and distributors to acquire controlled substances from authorized law enforcement agencies and certain collectors that have acquired controlled substances from ultimate users and other non-registrants. DEA proposes to require these registered reverse distributors and distributors

⁴⁷ The universe of potential participants includes all registrants that could potentially become authorized collectors. It is likely that this estimate will be adjusted downward once DEA obtains more information.

to maintain complete and accurate records of controlled substances received, delivered, or otherwise transferred for the purpose of destruction.

DEA estimates that the universe of potential respondents to this information collection will be 888 respondents (Distributors - 828, Reverse Distributors – 60). DEA estimates that the frequency of response will vary, because in accordance with 21 U.S.C. 827(a), registrants make an initial and biennial inventory and maintain, on a current basis, a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of. The authorization for reverse distributors and distributors to acquire controlled substances collected by law enforcement agencies and authorized collectors is new. As a result, DEA presently has no criterion to determine the level of participation and the annual hour burden cannot be determined at this time. DEA will continue to analyze the potential burden of the new requirements imposed by this proposed rule and review all comments submitted in response to this proposed rule and information collection request.

Title: Registrant Record of Controlled Substances Destroyed – DEA Form 41

OMB Control Number: 1117-0007

Form Number: DEA Form 41

The recordkeeping requirements that DEA registrants are required to maintain pursuant to law are a vital component of DEA's enforcement and control responsibilities – such records alert DEA to problems of diversion and ensure that the system of controlled substances distribution is open only to legitimate handlers of such substances. DEA is proposing information that registrants involved in the destruction of controlled substances must record. The record of destruction must include the signature of the two

authorized employees of the registrant that witnessed the destruction, in addition to other information about the controlled substance disposed of and the method of destruction utilized. DEA proposes to modify existing DEA Form 41 to reflect the proposed record of destruction for controlled substances that remain in the closed system of distribution and to account for registrant destruction of controlled substances collected from ultimate users and other non-registrants outside the closed system pursuant to the Disposal Act. DEA Form 41 has previously been approved by OMB and assigned OMB control number 1117-0007.

In accordance with the current 21 CFR 1307.21, a DEA registrant that desires to dispose of a controlled substance must submit three copies of DEA Form 41 to the Special Agent in Charge (SAC) in their area. DEA is proposing to delete 21 CFR 1307.21 and replace it with a comprehensive part 1317 on disposal. In an effort to minimize the burden on registrants and in accordance with the proposed comprehensive regulatory framework for disposal, registrants that destroy controlled substances and utilize DEA Form 41 will no longer be required to submit three copies of DEA Form 41 to the SAC in their area. Rather, in accordance with the CSA, such registrants will be required to keep and make available the information in the specified format, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General. 21 U.S.C. 827(b).

DEA estimates that there will be 68,344 respondents (Distributors - 828, Reverse Distributors - 60, Manufacturers - 522, Retail Pharmacies - 66,934) to this information collection. The number of respondents (68,344) represents the total number of registrants in business activities that are most likely to destroy controlled substances. DEA

estimates that the frequency of response will vary, because in accordance with 21 U.S.C. 827(a), registrants maintain, on a current basis, a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of and as a result will make a record of destruction each time they destroy a controlled substance. DEA estimates that the average time per response will be 30 minutes and that the total annual burden will be 34,172 hours.

Request for Comments Regarding the Proposed Information Collection

All estimates include the time for reviewing instructions; searching existing data sources; gathering or maintaining the needed data; and reviewing the information. DEA solicits comments concerning: whether these information collection requirements are necessary for the proper performance of the functions of DEA, including whether the information has practical utility; the accuracy of DEA's estimates of the burden of the information collection requirements; the quality, utility, and clarity of the information to be collected; and whether the burden of collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology, may be minimized. For information or a copy of the paperwork package submitted to OMB, contact John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 307-4654.

Organizations and individuals desiring to submit comments on the collection of information requirements should direct them to Drug Enforcement Administration, Attention: Office of Diversion Control (OD/DX), 8701 Morrisette Drive, Springfield, Virginia 22152.

OMB is required to make a decision concerning the collection of information requirements contained in this proposed rule between 30 and 60 days after its publication in the Federal Register. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

DEA is not authorized to impose a penalty on persons for violating information collection requirements which do not display a current OMB control number, if required. DEA intends to obtain current OMB control numbers for any new information collection requirements resulting from this rulemaking action prior to the effective date of the final rule. The OMB control number, when assigned, will be announced by separate notice in the Federal Register.

Executive Order 12988

This proposed regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law, impose enforcement responsibilities on any state or diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

National Environmental Policy Act (NEPA)

This proposed rule provides options for the collection of controlled substances by registrants and non-registrants consistent with DEA regulations and federal, state, tribal, and local laws and regulations. Provision of these options is intended to result in increased collection and destruction of unused controlled substances and thereby prevent diversion of such unused substances to illicit uses and result in collection and destruction of larger quantities in economical and environmentally sound manners. This proposed rule establishes the legal requirements for the handling of controlled substances.

Destruction of controlled substances must be consistent with federal, state, tribal and local laws and regulations.

DEA and the regulated community have disposed of controlled substances since passage of the CSA. DEA has published a categorical exclusion from further NEPA analysis for the storage and destruction of controlled substances. This proposed rule would not authorize any new methods of storage, transportation, or destruction of controlled substances, but is limited to the logistics and documentation of the collection of controlled substances for destruction. Accordingly, this proposed rule does not significantly affect the quality of the human environment. DEA has, therefore, determined that this proposed rule does not have significant individual or cumulative effects on the human environment and is excluded from detailed analysis pursuant to 28 CFR part 61, Appendix B.

Unfunded Mandates Reform Act

This proposed rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$136,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small

governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C 1532.

Executive Order 13175

This proposed rule is required by statute, will not have tribal implications and will not impose substantial direct compliance costs on Indian tribal governments.

List of Subjects

21 CFR Part 1300

Chemicals, Drug traffic control.

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

21 CFR Part 1304

Drug traffic control, Reporting and recordkeeping requirements.

21 CFR Part 1305

Drug traffic control.

21 CFR Part 1307

Drug traffic control.

21 CFR Part 1317

Drug traffic control, Reporting and recordkeeping requirements, Security measures.

For the reasons set forth above, DEA proposes to amend 21 CFR parts 1300, 1301, 1304, 1305, 1307, and 1317 as follows:

PART 1300—DEFINITIONS

1. The authority citation for part 1300 is revised to read as follows:

Authority: 21 U.S.C. 802, 821, 822, 829, 871(b), 951, 958(f).

2. Amend § 1300.01, in paragraph (b) by:

- a. Alphabetically adding a definition of “collection”;
- b. Revising the third sentence of the definition of “freight forwarding facility”;
- c. Alphabetically adding definitions of “non-retrievable” and “reverse distribute”; and
- d. Revising the definition of “reverse distributor”.

The additions and revisions read as follows:

§ 1300.01 Definitions relating to controlled substances.

* * * *

(b) * * *

Collection means to receive a controlled substance for the purpose of destruction from an ultimate user, a person lawfully entitled to dispose of ultimate user decedent’s property, or a long term care facility on behalf of an ultimate user that resides or has resided at that facility. The term collector means a registered manufacturer, distributor, reverse distributor, or retail pharmacy that is authorized under this chapter to so receive a controlled substance for the purpose of destruction.

* * *

Freight forwarding facility * * * For purposes of this definition, a distributing registrant is a person who is registered with the Administration as a manufacturer, distributor (excluding reverse distributor), and/or importer.

* * *

Non-retrievable means, for the purpose of destruction, the condition or state to which a controlled substance shall be rendered following a process that permanently

alters that controlled substance's physical and/or chemical condition or state through irreversible means and thereby renders the controlled substance unavailable and unusable for all practical purposes. The process to achieve a non-retrievable condition or state may be unique to a substance's chemical and/or physical properties. A controlled substance is considered "non-retrievable" when it cannot be transformed to a physical and/or chemical condition or state as a controlled substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes.

* * * * *

Reverse distribute means to acquire controlled substances from another DEA registrant or a law enforcement agency for the purpose of:

(1) Return to the registered manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf; or

(2) Destruction.

Reverse distributor means a person who reverse distributes a controlled substance.

* * *

* * * * *

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

3. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 953, 956, 957, 958.

4. Amend § 1301.13 by revising paragraph (e)(1)(i) to read as follows:

§ 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

* * * *

(e) * *

(1)

Business Activity	Controlled Substances	DEA Application Forms	Application Fee (\$)	Registration Period (years)	Coincident Activities Allowed
(i) Manufacturing	Schedules I – V	New–225 Renewal– 225a	3,047 3,047	1	Schedules I-V: May distribute that substance or class for which registration was issued; may not distribute any substance or class for which not registered. Schedules II-V: May conduct chemical analysis and preclinical research

					(including quality control analysis) with substances listed in those schedules for which authorization as a mfg. was issued.
*	*	*	*	*	*

* * * * *

5. Amend § 1301.25 by revising paragraph (i) to read as follows:

§ 1301.25 Registration regarding ocean vessels, aircraft, and other entities.

* * * * *

(i) Controlled substances acquired and possessed in accordance with this section shall be distributed only to persons under the general supervision of the medical officer employed by the owner or operator of the vessel, aircraft, or other entity, except in accordance with part 1317 of this chapter.

6. Revise § 1301.51 to read as follows:

§ 1301.51 Modification in registration.

(a) Any registrant may apply to modify his/her registration to authorize the handling of additional controlled substances, to change his/her name or address, or in the case of retail pharmacies, manufacturers, distributors, and reverse distributors, to authorize such registrant to be a collector, by submitting a letter of request to the

Registration Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(1) The letter shall contain:

(i) The registrant's name, address, and registration number as printed on the certificate of registration;

(ii) The substances and/or schedules to be added to the registration, a request for authorization to collect and the type(s) of collection the registrant intends to conduct (collection receptacle or mail-back program), or the new name or address; and

(iii) A signature in accordance with § 1301.13(j) of this part.

(2) If the registrant is seeking to handle additional controlled substances listed in Schedule I for the purpose of research or instructional activities, the registrant shall attach three copies of a research protocol describing each research project involving the additional substances, or two copies of a statement describing the nature, extent, and duration of such instructional activities, as appropriate.

(3) If a registered retail pharmacy is applying for a modification in registration to authorize such registrant to be a collector and maintain a collection receptacle at a long term care facility in accordance with § 1317.80 of this chapter, the registrant shall include the physical location of each long term care facility at which the registered pharmacy intends to operate a collection receptacle.

(b) No fee shall be required to be paid for modifications. The request for modification shall be handled in the same manner as an application for registration. If the modification in registration is approved, the Administrator shall issue a new certificate of registration (DEA Form 223) to the registrant, who shall maintain it with the old

certificate of registration until expiration.

7. Amend § 1301.52 by revising paragraph (c) to read as follows:

§ 1301.52 Termination of registration; transfer of registration; distribution upon discontinuance of business.

* * * * *

(c) Any registrant desiring to discontinue business activities altogether or with respect to controlled substances (without transferring such business activities to another person) shall return for cancellation his/her certificate of registration, and any unexecuted order forms in his/her possession, to the Registration Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for current mailing address. Any controlled substances in his/her possession may be disposed of in accordance with part 1317 of this chapter.

* * * * *

8. Amend 1301.72 by revising paragraph (a) introductory text to read as follows:

§1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.

(a) Schedules I and II. Raw material, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedule I or II (except GHB that is manufactured or distributed in accordance with an exemption under section 505(i) of the FFDCa which shall be subject to the requirements of paragraph (b) of this section), in addition to sealed mail-back packages and inner liners collected in accordance with part 1317 of this chapter, shall be stored in one of the following secured areas:

* * * * *

9. Amend § 1301.75 by revising paragraph (b) to read as follows:

§ 1301.75 Physical security controls for practitioners.

* * * * *

(b) Controlled substances listed in Schedules II, III, IV, and V, in addition to sealed mail-back packages and inner liners collected in accordance with part 1317 of this chapter, shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances, excluding sealed mail-back packages and collection receptacle inner liners, throughout the stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

* * * * *

10. Amend § 1301.76 by revising paragraph (c) to read as follows:

§ 1301.76 Other security controls for practitioners.

* * * * *

(c) Whenever the registrant distributes a controlled substance (as permitted in §§ 1301.13(e)(1), 1307.11, 1317.05, and 1317.10 of this chapter), he/she shall comply with the requirements imposed on non-practitioners in § 1301.74(a), (b), and (e).

* * * * *

PART 1304—RECORDS AND REPORTS OF REGISTRANTS

11. The authority citation for part 1304 is revised to read as follows:

Authority: 21 U.S.C. 821, 827, 831, 871(b), 958(f) and (g), and 965, unless otherwise noted.

12. Amend § 1304.03 by revising the first two sentences of paragraph (a) to read as follows:

§ 1304.03 Persons required to keep records and file reports.

(a) Each registrant shall maintain the records and inventories and shall file the reports required by this part and part 1317 of this chapter, except as exempted by this section. Any registrant who is authorized to conduct other activities without being registered to conduct those activities, pursuant to §§ 1301.22(b), 1307.11, or 1307.13 of this chapter, shall maintain the records and inventories and shall file the reports required by this part for persons registered to conduct such activities. *

* * * *

13. Amend § 1304.04 by revising paragraph (a) introductory text to read as follows:

§ 1304.04 Maintenance of records and inventories.

(a) Except as provided in paragraphs (a)(1) and (2) of this section, every inventory and other records required to be kept under this part and part 1317 of this chapter must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration.

* * * *

14. Amend § 1304.11 by revising paragraph (e) introductory text, paragraph (e)(2), and paragraph (e)(3) introductory text to read as follows:

§ 1304.11 Inventory requirements.

* * * *

(e) Inventories of manufacturers, distributors, dispensers, researchers,

importers, exporters and chemical analysts. Each person registered or authorized (by §§ 1301.13, 1307.11, or 1307.13 of this chapter) to manufacture, distribute, dispense, import, export, conduct research or chemical analysis with controlled substances and required to keep records pursuant to § 1304.03 shall include in the inventory the information listed below.

* * * * *

(2) Inventories of distributors. Except for reverse distributors covered by § 1317.25 of this chapter, each person registered or authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section.

(3) Inventories of dispensers and researchers. Each person registered or authorized to dispense or conduct research with controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section. In determining the number of units of each finished form of a controlled substance in a commercial container that has been opened, the dispenser or researcher shall do as follows:

* * * * *

15. Amend § 1304.22 by revising the introductory text, paragraph (b), and removing paragraph (e).

The revisions read as follows:

§ 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers and exporters.

Each person registered or authorized (by §§ 1301.13(e), 1307.11, or 1307.13 of

this chapter) to manufacture, distribute, dispense, import, export, or conduct research with controlled substances shall maintain records with the information listed below.

* * * * *

(b) Records for distributors. Except for reverse distributors covered by §§ 1317.25 and 1317.55 of this chapter, each person registered or authorized to distribute controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraphs (a)(2)(i), (ii), (iv), (v), (vii), (viii), and (ix) of this section or, when applicable, § 1317.55 of this chapter.

* * * * *

16. Amend § 1304.25 by revising paragraphs (a)(9) and (b)(9) to read as follows:

§ 1304.25 Records for treatment programs which compound narcotics for treatment programs and other locations.

* * * * *

(a) * * *

(9) The quantity disposed of by destruction, including the reason, date and manner of destruction. All other destruction of narcotic controlled substances shall comply with part 1317 of this chapter.

(b) * * *

(9) The number of units of finished forms and/or commercial containers destroyed in any manner by the registrant, including the reason, the date and manner of destruction. All other destruction of narcotic controlled substances shall comply with part 1317 of this chapter.

PART 1305—ORDERS FOR SCHEDULE I AND II CONTROLLED

SUBSTANCES

17. The authority citation for part 1305 continues to read as follows:

Authority: 21 U.S.C. 821, 828, 871(b), unless otherwise noted.

18. Amend § 1305.03 by adding paragraph (e) to read as follows:

§ 1305.03 Distributions requiring a Form 222 or a digitally signed electronic order.

* * * * *

(e) Deliveries to an authorized DEA registrant pursuant to part 1317 of this chapter by an ultimate user, a long-term care facility on behalf of an ultimate user that resides or has resided at that facility, or a person authorized to dispose of the ultimate user decedent's property .

PART 1307—MISCELLANEOUS

19. The authority citation for part 1307 continues to read as follows:

Authority: 21 U.S.C. 821, 822(d), 871(b), unless otherwise noted.

§ 1307.11 [Amended]

20. In § 1307.11, remove and reserve paragraph (a)(2).

§ 1307.12 [Removed]

21. Remove § 1307.12.

22. Revise § 1307.13 to read as follows:

§ 1307.13 Incidental manufacture of controlled substances.

Any registered manufacturer who, incidentally but necessarily, manufactures a controlled substance as a result of the manufacture of a controlled substance or basic class of controlled substance for which he is registered and has been issued an individual manufacturing quota pursuant to part 1303 of this chapter (if such substance or class is

listed in Schedule I or II) shall be exempt from the requirement of registration pursuant to part 1301 of this chapter and, if such incidentally manufactured substance is listed in Schedule I or II, shall be exempt from the requirement of an individual manufacturing quota pursuant to part 1303 of this chapter, if such substances are disposed of in accordance with part 1317 of this chapter.

§ 1307.21 [Removed]

23. Remove § 1307.21

24. Revise § 1307.22 to read as follows:

§ 1307.22 Delivery of surrendered and forfeited controlled substances.

Any controlled substance surrendered by delivery to the Administration under part 1317 of this chapter or forfeited pursuant to section 511 of the Act (21 U.S.C. 881) may be delivered to any department, bureau, or other agency of the United States or of any state upon proper application addressed to the Office of Diversion Control, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. The application shall show the name, address, and official title of the person or agency to whom the controlled drugs are to be delivered, including the name and quantity of the substances desired and the purpose for which intended. The delivery of such controlled drugs shall be ordered by the Administrator, if, in his opinion, there exists a medical or scientific need therefor.

25. Add part 1317 to read as follows:

PART 1317 – DISPOSAL

Sec.

1317.01 Scope.

1317.02 Definitions.

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SUBPART B - DISPOSAL OF CONTROLLED SUBSTANCES BY ULTIMATE USERS AND

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1317.55 Registered reverse distributor and distributor acquisition of controlled substances from law enforcement agencies or authorized collectors.

1317.60 Inner liner requirements.

- 1317.65 Take-back events.
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- 1317.75 Collection receptacles.
- 1317.80 Collection receptacles at long term care facilities.
- 1317.85 Ultimate user delivery for the purpose of recall or investigational use of drugs.

SUBPART C – DESTRUCTION OF CONTROLLED SUBSTANCES

- 1317.90 Methods of destruction.
- 1317.95 Destruction procedures.
- 1317.100 Recordkeeping requirements.

Authority: 21 U.S.C. 821; 822; 823; 827; 828; 871(b); and 958.

§ 1317.01 Scope.

This part prescribes the process and procedures for the delivery, collection, and destruction of damaged, expired, recalled, unused, or otherwise unwanted controlled substances that are lawfully possessed by DEA registrants (Subpart A) and non-registrants (Subpart B). The purpose of such procedures is to provide prompt, safe, and effective disposal methods while providing effective controls against the diversion of controlled substances.

§ 1317.02 Definitions.

- (a) As used in this part, the following terms shall have the meaning specified:

Authorized Employee means an individual employed full time by the registrant, who has not been convicted of a felony offense related to controlled substances and has not, at any time, had an application for registration with DEA denied, had a DEA

registration revoked or suspended, or surrendered a DEA registration for cause.

For cause means in lieu of, or as a consequence of, any federal or state administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances.

Inner liner means a liner that meets the specifications listed in § 1317.60 of this chapter and is used in the collection of controlled substances.

Law enforcement officer means a person that is:

- (i) Employed full time by a law enforcement agency;
- (ii) Under the direction and control of a federal, state, tribal, or local government;
- (iii) Acting in the course of their official duty; and
- (iv) Duly sworn and given the authority by any federal, state, tribal, or local government to carry firearms, execute and serve warrants, make arrests without warrant, and make seizures of property.

(b) Any other term contained in this part and not defined in paragraph (a) of this section shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

SUBPART A - DISPOSAL OF CONTROLLED SUBSTANCES BY REGISTRANTS

§ 1317.05 Registrant disposal.

(a) Practitioner Inventory. Any DEA registered practitioner in lawful possession of a controlled substance in its inventory who desires to dispose of that substance shall do so in one of the following ways:

- (1) Promptly destroy that controlled substance in accordance with subpart C of this part using an on-site method of destruction;

(2) Promptly deliver that controlled substance to a reverse distributor's registered location by common or contract carrier or by reverse distributor pick-up at the registrant's registered location;

(3) For the purpose of return or recall, promptly deliver that controlled substance by common or contract carrier or pick-up at the registrant's registered location to: the registered person from whom it was obtained, the registered manufacturer of the substance, or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf; or

(4) Request assistance from the Special Agent in Charge of the Administration in the area in which the practitioner is located.

(i) The request shall be made by submitting one copy of DEA Form 41 to the Special Agent in Charge in the practitioner's area. The DEA Form 41 shall list the controlled substance or substances which the registrant desires to dispose.

(ii) The Special Agent in Charge shall instruct the applicant to dispose of the controlled substance in one of the following manners:

(A) By transfer to a person registered under the Act and authorized to transport or destroy the substance;

(B) By delivery to an agent of the Administration or to the nearest office of the Administration; or

(C) By destruction in the presence of an agent of the Administration or other authorized person.

(iii) In the event that a practitioner is required regularly to dispose of controlled substances, the Special Agent in Charge may authorize the practitioner to dispose of such

substances, in accordance with subparagraph (a)(2) of this section, without prior application in each instance, on the condition that the practitioner keep records of such disposals and file periodic reports with the Special Agent in Charge summarizing the disposals. The Special Agent in Charge may place such conditions as she/he deems proper on practitioner procedures regarding the disposal of controlled substances.

(b) Non-practitioner inventory. Any DEA registrant who is a non-practitioner in lawful possession of a controlled substance in its inventory who desires to dispose of that substance shall do so in one of the following ways:

(1) Promptly destroy that controlled substance in accordance with Subpart C of this part using an on-site method of destruction;

(2) Promptly deliver that controlled substance to a reverse distributor's registered location by common or contract carrier or by reverse distributor pick-up at the registrant's registered location;

(3) For the purpose of return or recall, promptly deliver that controlled substance by common or contract carrier or pick-up at the registrant's registered location to: the registered person from whom it was obtained, the registered manufacturer of the substance, or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf; or

(4) Promptly transport that controlled substance by its own means to the registered location of a reverse distributor, the location of destruction, or the registered location of any person authorized to receive that controlled substance for the purpose of return or recall as described in paragraph (b)(3) of this section.

(i) If a non-practitioner transports controlled substances by its own means to the location of destruction, the non-practitioner shall follow the procedures set forth at § 1317.95(b).

(ii) If a non-practitioner transports controlled substances by its own means to a registered location for any other authorized purpose described in this paragraph (b)(4), transportation shall be directly to the authorized registered location and two authorized employees of the transporting non-practitioner shall accompany the controlled substances to the destination registered location.

(c) Collected Controlled Substances. Any authorized collector in lawful possession of a controlled substance acquired by collection from an ultimate user or other authorized non-registrant person shall dispose of that substance in the following ways:

(1) Mail-Back Program. Upon receipt of a sealed mail-back package, the authorized collector shall promptly:

(i) Destroy the package in accordance with Subpart C of this part using an on-site method of destruction; or

(ii) Securely store the package in a manner consistent with the security requirements for Schedule II controlled substances until prompt on-site destruction can occur or, with regard to the receipt of unauthorized packages, until instructions from the Administration are received.

(2) Collection Receptacles. Upon removal from the permanent outer shell, the authorized collector shall promptly:

(i) Destroy the inner liner and its contents; or

(ii) Store the inner liner and its contents at the collector's registered location in a manner consistent with the security requirements for Schedule II controlled substances until prompt destruction can occur.

(iii) Practitioner Methods of Destruction. Authorized collectors who are registered practitioners shall dispose of sealed inner liners and their contents by utilizing any method in § 1317.05(a)(1), (a)(2), or (a)(4), or by delivering sealed inner liners and their contents to a distributor's registered location by common or contract carrier or by distributor pick-up at the collector's authorized collection location for destruction.

(iv) Non-Practitioner Methods of Destruction. Authorized collectors who are non-practitioners shall dispose of sealed inner liners and their contents utilizing any method in § 1317.05(b)(1), (b)(2), or (b)(4), or by delivering sealed inner liners and their contents to a distributor's registered location by common or contract carrier or by distributor pick-up at the collector's authorized collection location for destruction. Except distributing registrants shall not utilize freight forwarding facilities to transfer sealed inner liners and their contents.

§ 1317.10 Registrant return or recall recordkeeping and order form requirements.

(a) Each registrant shall maintain a record of each return or recall transaction in accordance with part 1304 of this chapter.

(1) Each registrant that delivers a controlled substance to another registrant for the purpose of return or recall shall maintain a record pursuant to § 1304.22(b).

(2) Each registrant that receives a controlled substance for the purpose of return or recall shall maintain a record that includes the following information: the date of the

transaction; the name, form, and quantity of each controlled substance received; and the name, address, and registration number of the delivering registrant from whom the substance was received.

(b) Each registrant that delivers a controlled substance in Schedule I or II for the purpose of return or recall shall use an order form in the manner prescribed in part 1305 of this chapter.

(c) Deliveries for the purpose of return or recall may be made through a freight forwarding facility operated by the person to whom the controlled substance is being returned provided that advance notice of the return is provided and delivery is directly to an agent or employee of the person to whom the controlled substance is being returned.

§ 1317.15 Reverse distributor registration requirements and authorized activities.

(a) Any person that reverse distributes a controlled substance shall be registered with DEA as a reverse distributor, unless exempted by law or otherwise authorized pursuant to this chapter.

(b) A registered reverse distributor shall acquire controlled substances from a DEA registrant pursuant to §§ 1317.05 and 1317.55(a) in the following manner:

(1) The registered reverse distributor may pick-up controlled substances from a DEA registrant at the DEA registrant's registered location; or

(2) The registered reverse distributor may receive controlled substances delivered by common or contract carrier or delivered directly by a registrant who is a non-practitioner.

(i) Delivery to the registered reverse distributor by an authorized DEA registrant directly or by common or contract carrier may only be made to the reverse distributor at

the reverse distributor's registered location. Once en route, such deliveries may not be re-routed to any other location or person, regardless of registration status.

(ii) All controlled substance deliveries to a registered reverse distributor shall be personally received by an authorized employee of the reverse distributor at the registered location.

(c) Upon acquisition of a controlled substance by pick-up or delivery, a registered reverse distributor shall:

(1) Immediately and securely store the controlled substance at the reverse distributor's registered location, or immediately transfer the controlled substance to the reverse distributor's registered location for secure storage until timely destruction or timely return of the substance to the registered manufacturer or other registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf ;

(2) Immediately deliver the controlled substance to the registered manufacturer or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf;

(3) Timely destroy the controlled substance in a manner prescribed in Subpart C of this part; or

(4) Immediately deliver the controlled substance to the location of destruction for timely destruction pursuant to paragraph (d) of this section.

(d) A registered reverse distributor shall destroy or cause the destruction of any controlled substance received for the purpose of destruction as soon as practicable but no later than fourteen calendar days of receipt.

§ 1317.20 Reverse distributor employee security requirement.

A registered reverse distributor shall not employ, as an agent or employee who has access to or influence over controlled substances, any person who has been convicted of any felony offense relating to controlled substances or who, at any time, had an application for registration with DEA denied, had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause.

§ 1317.25 Reverse distributor inventory, recordkeeping, reporting, and order form requirements.

(a) A registered reverse distributor that acquires controlled substances from a registrant shall maintain the records, reports, and order forms described in this section and part 1304 of this chapter, except that a reverse distributor that acquires controlled substances from law enforcement agencies or authorized collectors pursuant to subpart B of this part shall follow § 1317.55(d) through (f) of this chapter.

(b) Inventory requirements. Each person registered as a reverse distributor shall include the following information in the inventory records required by § 1304.11 of this chapter:

- (1) The name of the substance; and
- (2) The total quantity of the substance:
 - (i) For controlled substances in bulk form, to the nearest metric unit weight consistent with unit size;
 - (ii) For each controlled substance in finished form: each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter); the number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and the number of commercial

containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials); and

(iii) For controlled substances in a commercial container, carton, crate, drum, or other receptacle that has been opened: if the substance is listed in Schedule I or II, make an exact count or measure of the contents; or if the substance is listed in Schedule III, IV or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents shall be made.

(c) Record requirements. Each person registered as a reverse distributor shall maintain records with the following information required by § 1304.21 of this chapter:

(1) For return or recall to manufacturers:

(i) The date of receipt; the name and quantity of each controlled substance received; the name, address, and DEA number of the person from whom the substance was received; and the reason for return (e.g., recall or return); and

(ii) The date of return to the manufacturer or other registrant authorized by the manufacturer to accept returns on the manufacturer's behalf; the name and quantity of each controlled substance returned; the name, address, and DEA number of the person from whom the substance was received; the name, address, and DEA number of the registrant to whom the substance was returned; and the method of return (e.g., common or contract carrier).

(2) For destruction:

(i) The date of receipt; the name and quantity of each controlled substance received; and the name, address, and DEA number of the person from whom the

substance was received; and

(ii) The date of destruction; the method of destruction; the name and quantity of each controlled substance destroyed; the name, address, and DEA number of the person from whom the substance was received; the place of destruction; and the name and signature of the two authorized employees of the registered reverse distributor that witnessed the destruction.

(3) The total quantity of each controlled substance shall be recorded in accordance with the following:

(i) For controlled substances in bulk form: to the nearest metric unit weight or volume consistent with unit size;

(ii) For controlled substances in finished form: each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter); the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and the number of commercial containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials); and

(iii) For controlled substances in a commercial container, carton, crate, drum, or other receptacle that has been opened: if the substance is listed in Schedule I or II make an exact count or measure of the contents; or if the substance is listed in Schedule III, IV or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents shall be made.

(4) For all records, the record of receipt shall be maintained together with the corresponding record of return or destruction.

(d) Reports to ARCOS. Registered reverse distributors shall report acquisition/distribution transactions pursuant to § 1304.33 of this chapter.

(e) Order forms. Each person registered to reverse distribute controlled substances in Schedules I or II shall comply with the requirements in part 1305 of this chapter.

**SUBPART B - DISPOSAL OF CONTROLLED SUBSTANCES BY ULTIMATE USERS AND
OTHER NON-REGISTRANTS**

§ 1317.30 Authorization to collect from non-registrants.

(a) The following persons are authorized to collect controlled substances from ultimate users and other non-registrants for destruction in compliance with this chapter:

(1) Any registrant authorized by DEA to be a collector pursuant to § 1317.40 of this chapter; and

(2) Any federal, state, tribal, or local law enforcement agency or any law enforcement officer employed thereby acting in the course of that person's official duties and pursuant to § 1317.35 of this chapter.

(b) The following non-registrant persons in lawful possession of a controlled substance in Schedules II, III, IV, or V may transfer that substance to the authorized persons listed in paragraph (a) of this section, and in a manner authorized by this part, for the purpose of disposal:

(1) An ultimate user in lawful possession of a controlled substance;

(2) Any person lawfully entitled to dispose of a decedent's property if that decedent was an ultimate user that died while in lawful possession of a controlled substance; and

(3) A long term care facility on behalf of an ultimate user who resides or resided at such long term care facility and is/was in lawful possession of a controlled substance in accordance with § 1317.80 of this chapter only.

§ 1317.35 Collection by law enforcement agencies.

(a) A Federal, state, tribal, or local law enforcement agency may collect controlled substances from ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property using the following collection methods:

- (1) Take-back events in accordance with § 1317.65 of this chapter;
- (2) Mail-back programs in accordance with § 1317.70 of this chapter; or
- (3) Collection receptacles located at the law enforcement agency's physical address and in accordance with § 1317.75 of this chapter.

(b) A law enforcement agency that conducts a take-back event or a mail-back program or maintains a collection receptacle should maintain any records of removal, storage, or destruction of the controlled substances collected in a manner that is consistent with that agency's recordkeeping requirements for illicit controlled substances evidence.

(c) Any controlled substances collected by a law enforcement agency through a take-back event, mail-back program, or collection receptacle should be stored in a manner that prevents the diversion of controlled substances and is consistent with that agency's standard procedures for storing illicit controlled substances.

(d) Any controlled substances collected by a law enforcement agency through a take-back event, mail-back program, or collection receptacle should be transferred to a destruction location in a manner that prevents diversion.

(e) A law enforcement agency that transfers controlled substances collected from ultimate users pursuant to this part to a reverse distributor for destruction should maintain a record that contains the following information: if an inner liner as described in § 1317.60 of this chapter is used, the unique identification number of the inner liner transferred, the size of the inner liner transferred (e.g., 5 gallon, 10 gallon, etc.); if a mail-back package as described in § 1317.70 is used, the unique identification number of each package; the date of the transfer; and the name, address, and DEA registration number of the reverse distributor to whom the controlled substances were transferred.

§ 1317.40 Registrants authorized to collect and authorized collection activities.

(a) Manufacturers, distributors, reverse distributors, and retail pharmacies may apply to modify their registration to obtain authorization to be a collector in accordance with § 1301.51 of this chapter. Authorization to be a collector is subject to renewal. If a registrant who is authorized to collect ceases activities as a collector, such registrant shall apply to modify its registration in accordance with § 1301.51 of this chapter to indicate that the registrant no longer collects.

(b) Collection by registrants shall occur only at the following locations:

(1) Those registered locations of manufacturers, distributors, reverse distributors, and retail pharmacies that are authorized for collection; and

(2) Long term care facilities at which registered retail pharmacies are authorized to maintain collection receptacles.

(c) Authorized collectors may conduct the following activities:

(1) Receive mail-back packages at a registered location that has an on-site method of destruction pursuant to § 1317.70 of this chapter;

(2) Install, manage, and maintain collection receptacles located at their authorized collection location(s); and

(3) Promptly dispose of sealed inner liners and their contents as provided for in § 1317.05(c)(2).

§ 1317.45 Collector security requirements.

An authorized collector shall not employ, as an agent or employee who has access to or influence over controlled substances acquired by collection, any person who has been convicted of any felony offense relating to controlled substances or who, at any time, had an application for registration with DEA denied, had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause.

§ 1317.50 Collector inventory, recordkeeping, reporting, and order form requirements.

(a) Inventory record requirements. Each authorized collector shall maintain the following information in the inventory:

(1) For registrants authorized to collect through a mail-back program, the record shall include the following information about each unused mail-back package and each returned mail-back package on hand awaiting destruction:

- (i) The date of the inventory;
- (ii) The number of mail-back packages; and
- (iii) The unique identification number of each package on hand, whether unused or awaiting destruction.

(2) For registrants authorized to collect through a collection receptacle, the record shall include the following information about each unused inner liner on hand and

each inner liner on hand awaiting destruction:

- (i) The date of the inventory;
- (ii) The number of inner liners;
- (iii) The unique identification number of each inner liner; and
- (iv) The size (e.g., 5 gallon, 10 gallon, etc.) of each inner liner.

(b) Continuing record requirements. Each authorized collector shall maintain the following records:

(1) For registrants authorized to collect through a mail-back program, the record shall include the following:

(i) For those unused packages that the collector makes available to ultimate users and other authorized non-registrants at the authorized collector's registered address: the date made available, the number of packages, and the unique identification number of each package;

(ii) For those unused packages provided to a third party to make available to ultimate users and other authorized non-registrants (e.g., a pharmacy, grocery store, etc.): the name of the third party and physical address of the location receiving the unused packages, date sent, and the number of unused packages sent with the corresponding unique identification numbers;

(iii) Upon receipt of a sealed package: the date of receipt and the unique identification number on the individual package; and

(iv) Upon destruction of a sealed package pursuant to Subpart C of this chapter: in accordance with the recordkeeping requirements in § 1317.100 of this chapter.

(2) For registrants authorized to collect through a collection receptacle, the record

shall include the following:

(i) Upon acquisition of each inner liner: the date the inner liner is acquired, the corresponding unique identification number of each inner liner, and the size (e.g., 5 gallon, 10 gallon, etc.) of each inner liner.

(ii) Upon installation of each inner liner in a collection receptacle: the date of installation, the address and DEA registration number of the location of the collection receptacle where the inner liner is installed, the unique identification number of the inner liner, the size of the inner liner (e.g., 5 gallon, 10 gallon, etc.), and the name of two authorized employees who witnessed the installation;

(iii) Upon removal of the inner liner: the date of removal, the address and DEA registration number of the collection location, the unique identification number of the inner liner, the size of the inner liner (e.g., 5 gallon, 10 gallon, etc.), and the name of two authorized employees who witnessed the removal;

(iv) Upon secure storage of a sealed inner liner: the date of the transfer to storage, the unique identification number of the inner liner stored, the size of the inner liner stored (e.g., 5 gallon, 10 gallon, etc.), and the name of two authorized employees who transferred the inner liner to secure storage;

(v) Upon transfer of a sealed inner liner to a reverse distributor or distributor: the date of the transfer, the address and DEA registration number of the reverse distributor or distributor to whom the inner liner was transferred, the unique identification number of the inner liner transferred, the size of the inner liner transferred (e.g., 5 gallon, 10 gallon, etc.), and the name of the two authorized employees who transferred the inner liner to the reverse distributor or distributor; and

(vi) Upon destruction pursuant to subpart C of this chapter: in accordance with the recordkeeping requirements in § 1317.100 of this chapter.

(c) Reports to ARCOS. Authorized collectors are exempt from the ARCOS reporting requirements in § 1304.33 of this chapter for controlled substances collected through mail-back programs and collection receptacles for the purpose of disposal.

(d) Order forms. Authorized collectors are exempt from the requirements in part 1305 of this chapter for controlled substances collected through mail-back programs and collection receptacles for the purpose of disposal.

§ 1317.55 Registered reverse distributor and distributor acquisition of controlled substances from law enforcement agencies or authorized collectors.

(a) A registered reverse distributor is authorized to acquire controlled substances from law enforcement agencies that collect controlled substances from ultimate users. A registered reverse distributor is authorized to acquire controlled substances from authorized collectors that collect controlled substances through a collection receptacle in accordance with §§ 1317.75 and 1317.80 of this chapter.

(b) A registered distributor is authorized to acquire controlled substances from authorized collectors that collect controlled substances through a collection receptacle pursuant to §§ 1317.75 and 1317.80 of this chapter.

(c) A registered reverse distributor or a registered distributor that acquires controlled substances in accordance with paragraphs (a) or (b) of this section shall:

(1) Acquire the controlled substances in the manner prescribed in § 1317.15(b) of this part;

(2) Dispose of the controlled substances in the following manner:

(i) Immediately and securely store the controlled substance at the reverse distributor's registered location, or immediately transfer the controlled substances to the reverse distributor's registered location for secure storage, until timely destruction; or

(ii) Immediately deliver the controlled substance to the location of destruction for timely destruction.

(iii) Destroy, or cause the controlled substances to be destroyed, as soon as practicable but no later than fourteen calendar days of receipt.

(iv) Destruction shall be in accordance with Subpart C of this part.

(3) Secure storage of the controlled substances shall be in a manner consistent with the security requirements for Schedule II controlled substances until timely destruction can occur.

(d) Record requirements. A registered reverse distributor or a registered distributor that acquires controlled substances pursuant to paragraphs (a) or (b) of this section shall maintain the following records:

(1) Upon receipt: the date of receipt; the name and address of the law enforcement agency or the name, address, and DEA registration number of the authorized collector from whom the inner liner (or mail-back package if from a law enforcement agency) was received; the unique identification number of the inner liner (or mail-back package if from a law enforcement agency) received; and the size of the inner liner received (e.g., 5 gallon, 10 gallon, etc.);

(2) Upon transfer to secure storage: the date of storage; the address and DEA number of the storage location; the unique identification number of the inner liner or mail-back package stored (if available in the case of a law enforcement agency); and the

size of the inner liner stored (e.g., 5 gallon, 10 gallon, etc.);

(e) Reports to ARCOS. Reverse distributors and distributors that acquire controlled substances pursuant to paragraphs (a) or (b) of this section are exempt from the ARCOS reporting requirements in § 1304.33 of this chapter with regard to any controlled substances acquired pursuant to paragraphs (a) or (b) of this section.

(f) Order forms. Reverse distributors and distributors that acquire controlled substances pursuant to paragraphs (a) or (b) of this section are exempt from the requirements in part 1305 of this chapter with regard to any controlled substances acquired pursuant to paragraphs (a) or (b) of this section.

§ 1317.60 Inner liner requirements.

For the purpose of part 1317 of this chapter, an inner liner shall fulfill the following requirements:

- (a) The inner liner shall be waterproof, tamper-evident, and tear-resistant;
- (b) The inner liner shall be removable and sealable immediately upon removal without emptying or touching the contents;
- (c) The contents of the inner liner shall not be viewable from the outside when sealed;
- (d) The size of the inner liner shall be clearly marked on the outside of the liner (e.g., 5 gallon, 10 gallon, etc.); and
- (e) The inner liner shall bear a permanent, unique identification number that enables the liner to be tracked.

§ 1317.65 Take-back events.

- (a) Any Federal, state, tribal, or local law enforcement agency may conduct a

take-back event and collect controlled substances from ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property in accordance with this section. Any person may partner with a law enforcement agency to hold a collection take-back event in accordance with this section.

(b) The law enforcement agency shall appoint a law enforcement officer employed full time by the agency to oversee the collection. Law enforcement officers employed and authorized by the law enforcement agency conducting a take-back event shall maintain control and custody of the collected substances from the time the substances are collected from the ultimate user or person authorized to dispose of the ultimate user decedent's property until secure transfer, storage, or destruction of the controlled substance has occurred.

(c) Each take-back event should have at least one receptacle for the collection of permitted substances. The collection receptacle should be a securely locked, substantially constructed container with an outer shell and a removable inner liner as specified in § 1317.60 of this chapter. The outer shell should include a small opening that allows contents to be added to the inner liner, but that does not allow removal of the inner liner's contents.

(d) Only those controlled substances listed in Schedule II, III, IV, or V that are lawfully possessed by an ultimate user or person entitled to dispose of an ultimate user decedent's property may be collected. Controlled and non-controlled substances may be collected together and be comingled.

(e) Only ultimate users and persons entitled to dispose of an ultimate user decedent's property in lawful possession of a controlled substance in Schedule II, III, IV,

or V may transfer such substances to the law enforcement agency during the take-back event. No other person may handle the controlled substances at any time.

§ 1317.70 Mail-back programs.

(a) A mail-back program may be conducted by any federal, state, tribal, or local law enforcement agency or any authorized collector. An authorized collector conducting a mail-back program shall have and utilize at their registered location a method of destruction consistent with § 1317.90 of this chapter.

(b) Only those controlled substances listed in Schedule II, III, IV, or V that are lawfully possessed by an ultimate user or person lawfully entitled to dispose of an ultimate user decedent's property may be collected. Controlled and non-controlled substances may be collected together and be comingled.

(c) A law enforcement agency or authorized collector that conducts a mail-back program shall make packages available (for sale or for free) as specified in this paragraph to ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property, for the collection of controlled substances by mail. Any person may partner with an authorized collector or law enforcement agency to make such packages available in accordance with this section. The packages made available shall meet the following specifications:

(1) The package shall be nondescript and shall not include any markings or other information that might indicate that the package contains controlled substances;

(2) The package shall be water- and spill-proof; tamper-evident, tear-resistant, and sealable;

(3) The package shall be preaddressed with and delivered to the authorized

collector's registered address or the participating law enforcement agency's physical address;

(4) The cost of shipping the package shall be postage paid;

(5) The package shall have a unique identification number that enables the package to be tracked; and

(6) The package shall include instructions for the user that indicate the process for mailing back the package, the permitted substances that can be sent, and notice that only packages provided by the authorized collector will be accepted for destruction.

(d) Ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property shall not be required to provide any personally identifiable information when mailing back controlled substances to an authorized collector. The authorized collector or law enforcement agency may implement a system that allows ultimate users or persons lawfully entitled to dispose of an ultimate user decedent's property to notify the collector or agency that they are sending one of the designated packages by giving the unique identification number on the package.

(e) An authorized collector that conducts a mail-back program pursuant to paragraph (a) shall:

(1) Accept only those controlled substances contained within packages that the collector made available for the collection of controlled substances by mail.

(2) Within three business days of receipt, notify the Field Division Office of the Administration in their area of the receipt of a package that likely contains controlled substances and that the authorized collector did not make available for the collection of controlled substances by mail.

(f) Only law enforcement officers employed by the law enforcement agency and authorized employees of the collector shall handle packages received through an authorized mail-back program. Upon receipt of a mail-back package by an authorized collector conducting a mail-back program, the package shall not be opened, x-rayed, analyzed, or otherwise penetrated.

§ 1317.75 Collection receptacles.

(a) Any federal, state, tribal, or local law enforcement agency or authorized collector may manage, maintain, and empty collection receptacles for disposal.

(b) Only those controlled substances listed in Schedule II, III, IV, or V that are lawfully possessed by an ultimate user or other authorized non-registrant person may be collected. Controlled and non-controlled substances may be collected together and be comingled.

(c) Only ultimate users and other authorized non-registrant persons in lawful possession of a controlled substance in Schedule II, III, IV, or V may put such substances in a collection receptacle at a registered location (e.g., ultimate user cannot transfer such substance to pharmacy staff to put into a collection receptacle).

(d) Collection receptacles shall be securely placed and maintained:

(1) At an authorized collector's registered location, which shall have proper building security in accordance with §§ 1301.71 to 1301.77 of this chapter;

(2) At a long term care facility in accordance with § 1317.80 of this chapter; or

(3) At a law enforcement agency's physical location.

(e) For authorized collectors, a controlled substance collection receptacle shall:

(1) Be securely fastened to a permanent structure so that it cannot be removed;

(2) At a registered location, be located in the immediate proximity of a designated area where controlled substances are stored and at which an authorized employee is present (e.g., can be seen from the pharmacy counter); or at a long term care facility pursuant to § 1317.80, be located in a secured area regularly monitored by personnel of that long term care facility;

(3) Meet the following design specifications:

(i) A securely locked, substantially constructed container with a permanent outer shell and a removable inner liner as specified in § 1317.60 of this chapter.

(ii) The outer container shall include a small opening that allows contents to be added to the inner liner, but does not allow removal of the inner liner's contents;

(iii) The outer container shall prominently display a sign indicating that only non-controlled drugs and Schedule II, III, IV, or V controlled substances are acceptable (Schedule I controlled substances, controlled substances that are not lawfully possessed by the ultimate user, and other illicit or dangerous substances are not permitted); and

(iv) Access to the inner liner shall be restricted to authorized employees of the authorized collector.

(f) At a registered location, the small opening in the outer container of the collection receptacle shall be locked or made otherwise inaccessible to the public when an authorized employee is not present (e.g., when the pharmacy is closed).

(g) The installation and removal of the inner liner of the collection receptacle shall be performed by or under the supervision of at least two authorized employees of the authorized collector. The inner liner shall be sealed immediately upon removal from the permanent outer shell and the sealed inner liner shall not be opened, x-rayed,

analyzed, or otherwise penetrated.

§ 1317.80 Collection receptacles at long term care facilities.

(a) A long term care facility may dispose of controlled substances in Schedules II, III, IV, and V on behalf of an ultimate user who resides or resided at such long term care facility when such disposal occurs immediately, but no longer than three business days after the discontinuation of use by the ultimate user. A long term care facility shall dispose of such controlled substances only by transferring those controlled substances into an authorized collection receptacle located at that long term care facility.

(b) Only a registered retail pharmacy authorized to collect at the long term care facility may manage and maintain collection receptacles at that long term care facility and remove or supervise the removal of the inner liner of the collection receptacles at that long term care facility in accordance with § 1317.75(g) of this chapter. The registered retail pharmacy shall comply with all other requirements in § 1317.75 of this chapter.

(c) A registered retail pharmacy that intends to operate a collection receptacle at a long term care facility shall apply to modify its registration in accordance with § 1301.51 of this chapter and shall include in the application for modification in registration the physical location of each long term care facility at which the registered pharmacy intends to operate a collection receptacle.

§ 1317.85 Ultimate user delivery for the purpose of recall or investigational use of drugs.

(a) In the event of a product recall, an ultimate user in lawful possession of a controlled substance listed in Schedule II, III, IV, or V may deliver the recalled substance to the manufacturer of the substance or another registrant authorized by the manufacturer

to accept recalled controlled substances on the manufacturer's behalf.

(1) Continuing record requirements. Such registrant accepting recalled controlled substances shall maintain a record of each recalled controlled substance received from an ultimate user, to include the following information: the date of receipt, and the name, form, and quantity of each controlled substance received.

(2) Order forms. Such registrant accepting recalled controlled substances is exempt from the requirements in part 1305 of this chapter for the receipt of recalled controlled substances from ultimate users.

(3) Reports to ARCOS. Such registrant accepting recalled controlled substances may report as a single transaction all recalled controlled substances of the same name and finished form (e.g., all 10-milligram tablets or all 5-milligram concentration per fluid ounce or milliliter) received from ultimate users for the purpose of reporting acquisition transactions pursuant to § 1304.33 of this chapter.

(b) An ultimate user that is participating in an investigational use of drugs pursuant to 21 U.S.C. 355(i) and 360b(j) and wishes to deliver any unused controlled substances received as part of that research to the registered dispenser from which the ultimate user obtained those substances may do so in accordance with regulations promulgated by the Secretary of Health and Human Services pursuant to 21 U.S.C. 355(i) and 360b(j).

SUBPART C - DESTRUCTION OF CONTROLLED SUBSTANCES

§ 1317.90 Methods of destruction.

(a) All controlled substances to be destroyed shall be destroyed in compliance with applicable federal, state, tribal, and local laws and regulations and shall be rendered

non-retrievable.

(b) Where multiple controlled substances are comingled, the method of destruction shall be sufficient to render all such controlled substances non-retrievable. When the actual substances collected for destruction are unknown but may reasonably include controlled substances, the method of destruction shall be sufficient to render non-retrievable any controlled substance likely to be present.

(c) The method of destruction shall be consistent with the purpose of rendering all controlled substances to a non-retrievable state in order to prevent diversion of any such substance to illicit purposes and to protect the public health and safety.

§ 1317.95 Destruction procedures.

The destruction of any controlled substance shall be in accordance with the following requirements:

(a) If the controlled substances are transferred to a person registered under the Act and authorized to accept the controlled substances for purposes of disposal, two authorized employees of the transferring registrant shall load and unload or observe the loading and unloading of any controlled substances until transfer is complete.

(b) If the controlled substances are transported by a registrant to the location of destruction, the following procedures shall be followed:

(1) Transportation shall be directly to the destruction location;

(2) Two authorized employees of the transporting registrant shall accompany the controlled substances to the destruction location;

(3) Two authorized employees of the transporting registrant shall load and unload or observe the loading and unloading of the controlled substances;

- (4) Two authorized employees of the transporting registrant shall handle or observe the handling of any controlled substance until the substance is rendered non-retrievable; and
 - (5) Two authorized employees of the transporting registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable.
- (c) If the controlled substances are destroyed at a registrant's registered location utilizing an on-site method of destruction, the following procedures shall be followed:
- (1) Two authorized employees of the registrant shall handle or observe the handling of any controlled substance until the substance is rendered non-retrievable; and
 - (2) Two authorized employees of the registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable.

§ 1317.100 Recordkeeping requirements.

(a) In addition to any other recordkeeping requirements, any registered person that destroys or causes the destruction of a controlled substance shall maintain a record of destruction on a form issued by DEA that includes the following information: the date of destruction; the method of destruction; the name and address of the place of destruction; the name and quantity of the controlled substances destroyed or the unique identification number of the inner liner or mail-back package destroyed; the size of the inner liner destroyed (e.g., 5 gallon, 10 gallon, etc.); and the name and signature of the two authorized employees who witnessed the destruction.

(b) If the controlled substances destroyed were received from another registrant, the registrant destroying the controlled substances shall maintain a copy of the record transferring the substances or a copy of the DEA Form 222.

December 17, 2012

Dated:

Michele M. Leonhart
Administrator

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